24th Annual National Conference on Managing Environmental Quality Systems

8:30 – 12:00 TUESDAY, APRIL 12TH - A.M. Stockholder Meetings

12:00 – 4:30 TUESDAY, APRIL 12TH
Opening Plenary (Salons A-H)

- Opening Address
  - Reggie Cheatham, Director, OEI Quality Staff, EPA
  - Linda Travers, Principal Deputy Assistant Administrator, OEI, EPA
- Invited Speakers
  - Tom Huetteman, Deputy Assistant Regional Administrator, EPA Region 9
  - John Robertus, Executive Officer of San Diego Regional Water Quality Control Board, Region 9
- Keynote Address
  - Thomas Redman, President, Navesink Consulting Group
- Panel Sessions
- **Value of the Data Quality Act—Perspectives from OMB, Industry, and EPA (VDQA)**
  - Nancy Beck, OMB
  - Jamie Conrad, American Chemistry Council
  - Reggie Cheatham, Director, OEI Quality Staff, EPA
- **Wadeable Streams: Assessing the Quality of the Nation's Streams (WS)**
  - Margo Hunt, Panel Moderator
  - Mike Shapiro, Deputy Assistant Administrator, Office of Water
  - Steve Paulsen, Research Biologist, ORD

8:30 – 10:00 WEDNESDAY, APRIL 13TH
Environmental Measures (EM) (Salons A-C) *Chair: L. Bradley, EPA*

- Data Error Reduction by Automation throughout the Data Workflow Process (A. Gray, EarthSoft, Inc.)
- Analytical Approaches to Meeting New Notification Levels for Organic Contaminants in Calif. (D.Wijekoon, Calif. DHS)
- Streamlining Data Management and Communications for the Former Walker AFB Project (R. Amano, Lab Data Consultants, Inc.)

Quality System Implementation in the Great Lakes Program (QSI-GLP) (Salon D) *Chair: M. Cusanelli, EPA*

- GLNPO's Quality System Implementation for the New "Great Lakes Legacy Act for Sediment Remediation"(L. Blume, EPA)
- Black Lagoon Quality Plan Approval by GLNPO, MDEQ, ERRS, and USACE (J. Doan, Environmental Quality Management, Inc.)
- Remediation of the Black Lagoon Trenton Channel . . . Postdredging Sampling & Residuals Analysis (J. Schofield, CSC)

Quality Systems Models (QSM) (Salons F-H) *Chair: G. Johnson, EPA*

- Improving E4 Quality System Effectiveness by Using ISO 9001: 2000 Process Controls (C. Hedin, Shaw Environmental)

Applications of Novel Techniques to Environmental Problems (ANTEP) (Salon E) *Chair: B. Nussbaum, EPA*

- On Some Applications of Ranked Set Sampling (B. Sinha, University of Maryland)
- Combining Data from Many Sources to Establish Chromium Emission Standards (N. Neerchal, University of Maryland)
- Estimating Error Rates in EPA Databases for Auditing Purposes (H. Lacayo, Jr., EPA)
- Spatial Population Partitioning Using Voronoi Diagrams For Environmental Data Analysis (A. Singh, UNLV)

Ambient Air Session I (Sierra 5&6) *Chair: M.Papp, EPA*

- Changes and Improvements in the Ambient Air Quality Monitoring Program Quality System (M. Papp, EPA)
- Guidance for a New Era of Ambient Air Monitoring (A. Kelley, Hamilton County DES)
- Environmental Monitoring QA in Indian Country (M. Ronca-Battista, Northern Arizona University)
- Scalable QAPP IT Solution for Air Monitoring Programs (C. Drouin, Lake Environmental Software)

10:30 – 12:00 WEDNESDAY, APRIL 13TH

Environmental Laboratory Quality Systems (ELQS) (Salons A-C) *Chair: L. Bradley, EPA*

- A Harmonized National Accreditation Standard: The Next Step for INELA Field Activities (D. Thomas, Professional Service Industries, Inc.)
- Development of a Comprehensive Quality Standard for Environmental Laboratory Accreditation (J. Parr, INELA)
- Advanced Tracking of Laboratory PT Performance and Certification Status with Integrated Electronic NELAC-Style Auditing Software (T. Fitzpatrick, Lab Data Consultants, Inc.)

Performance Metrics (PM) (Salon D) *Chair: L. Doucet, EPA*

- Formulating Quality Management Metrics for a State Program in an Environmental Performance Partnership Agreement (P. Mundy, EPA)
- How Good Is "How Good Is?" (Measuring QA) (M. Kantz, EPA)
- Performance-Based Management (J. Santillan, US Air Force)

Quality Assurance Plan Guidance Initiatives (QAPGI) (Salons F-H) *Chair: A. Batterman, EPA*

- A CD-ROM Based QAPP Preparation Tool for Tribes (D. Taylor, EPA)
- Military Munitions Response Program Quality Plans (J. Sikes, U.S. Army)

Ask a Statistician: Panel Discussion (Salon E) *Moderator: B. Nussbaum, EPA* Panelists:

- Mike Flynn, Director, Office of Information Analysis and Access, OEI, EPA
- Reggie Cheatham, Director, Quality Staff, OEI, EPA
- Tom Curran, Chief Information Officer, OAQPS, EPA
- Diane Harris, Quality Office, Region 7, EPA
- Bill Hunt, Visiting Senior Scientist, North Carolina State University (NCSU)
- Rick Linthurst, OIG, EPA

Ambient Air Session II (Sierra 5&6) *Chair: M. Papp, EPA*

- National Air Toxics QA System and Results of the QA Assessment (D. Mikel, EPA)
- Technical System Audits (TSAs) and Instrument Performance Audits (IPAs) of the National Air Toxics Trends Stations (NATTS) and Supporting Laboratories (S. Stetzer Biddle, Battelle)
- Interlaboratory Comparison of Ambient Air Samples (C. Pearson, CARB)
- Developing Criteria for Equivalency Status for Continuous PM2.5 Samplers (B. Coutant, Battelle)

1:00 – 2:30 WEDNESDAY, APRIL 13TH

Environmental Laboratory Quality (ELQ) (Salons A-C) *Chair: L. Doucet, EPA*

- Environmental Laboratory Quality Systems: Data Integrity Model and Systematic Procedures (R. DiRienzo, DataChem Laboratories, Inc.)
- The Interrelationship of Proficiency Testing, Interlaboratory Statistics and Lab QA Programs (T. Coyner, Analytical Products Group, Inc.)
- EPA FIFRA Laboratory Challenges and Solutions to Building a Quality System in Compliance with International Laboratory Quality Standard ISO 17025 (A. Ferdig, Mich. Dept. of Agriculture)

Performance—Quality Systems Implementation (P-QSI) (Salon D) *Chair: A. Belle, EPA*

- Implementing and Assessing Quality Systems for State, Tribal, and Local Agencies (K. Bolger, D. Johnson, L. Blume, EPA)

1:00 – 2:30 WEDNESDAY, APRIL 13TH (continued)

Quality Initiatives in the EPA Office of Environmental Information (QI-OEI) (Salons F-H) *Chair: J. Worthington, EPA*

- Next Generation Data Quality Automation in EPA Data Marts (P. Magrogan, Lockheed)
- The Design and Implementation of a Quality System for IT Products and Services (J. Scalera, EPA)
- Data Quality is in the Eyes of the Users: EPA's Locational Data Improvement Efforts (P. Garvey, EPA)

A Win-Win-Win Partnership for Solving Environmental Problems (W3PSEP) (Salon E) *Co-Chairs: W. Hunt, Jr. and K. Weems, NCSU*

- Overview of Environmental Statistics Courses at NCSU (B. Hunt, NCSU Statistics Dept.)
- Overview of the Environmental Statistics Program at Spelman College (N. Shah, Spelman)
- Student presentations: H. Ferguson and C. Smith of Spelman College; C. Pitts, B. Stines and J. White of NCSU

Ambient Air Session III (Sierra 5&6) *Chair: M. Papp, EPA*

- Trace Gas Monitoring for Support of the National Air Monitoring Strategy (D. Mikel, EPA)
- Comparison of the Proposed Versus Current Approach to Estimate Precision and Bias for Gaseous Automated Methods for the Ambient Air Monitoring Program (L. Camalier, EPA)
- Introduction to the IMPROVE Program's New Interactive Web-based Data Validation Tools (L. DeBell, Colorado State University)
- The Role of QA in Determination of Effects of Shipping Procedures for PM2.5 Speciation Filters (D. Crumpler, EPA)

3:00 – 4:30 WEDNESDAY, APRIL 13TH

Topics in Environmental Data Operations (TEDO) (Salons A-C) *Chair: M. Kantz, EPA*

- Ethics in Environmental Operations: It's More Than Just Lab Data (A. Rosecrance, Laboratory Data Consultants, Inc.)
- QA/QC of a Project Involving Cooperative Agreements, IAGs, Agency Staff and Contracts to Conduct the Research (A. Batterman, EPA)
- Dealing with Fishy Data: A Look at Quality Management for the Great Lakes Fish Monitoring Program (E. Murphy, EPA)

Quality System Development (QSD) (Salon D) *Chair: A. Belle, EPA*

- Development of a QA Program for the State of California (B. van Buuren, Van Buuren Consulting, LLC)
- Integrating EPA Quality System Requirements with Program Office Needs for a Practical Approach to Assuring Adequate Data Quality to Support Decision Making (K. Boynton, EPA)
- Introducing Quality System Changes in Large Established Organizations (H. Ferguson, EPA)

Auditor Competence (AC) (Salons F-H) *Chair: K. Orr, EPA*

- Determining the Competence of Auditors (G. Johnson, EPA)

To Detect or Not Detect—What Is the Problem? (TDND) (Salon E) *Chair: J. Warren, EPA*

- A Bayesian Approach to Measurement Detection Limits (B. Venner)
- The Problem of Statistical Analysis with Nondetects Present (D. Helsel, USGS)
- Handling Nondetects Using Survival Anal.(D. Helsel, USGS)
- Assessing the Risk associated with Mercury: Using ReVA's Webtool to Compare Data, Assumptions and Models (E. Smith, EPA)

Ambient Air Session IV (Sierra 5&6) *Chair: M. Papp, EPA*

- Status and Changes in EPA Infrastructure for Bias Traceability to NIST (M. Shanis, EPA)
- Using the TTP Laboratory at Sites with Higher Sample Flow Demands (A. Teitz, EPA)

5:00 – 6:00 PM WEDNESDAY, APRIL 13TH

EPA SAS Users Group Meeting Contact: Ann Pitchford, EPA

8:30 – 10:00 THURSDAY, APRIL 14TH

Evaluating Environmental Data Quality (EEDQ) *(Salons A-C) Chair: M. Kantz, EPA*

- QA Documentation to Support the Collection of Secondary Data (J. O'Donnell, Tetra Tech, Inc.)
- Staged Electronic Data Deliverable: Overview and Status (A. Mudambi, EPA)
- Automated Metadata Reports for Geo-Spatial Analyses (R. Booher, INDUS Corporation)

Satellite Imagery QA (SI-QA) (Salon D) *Chair: M. Cusanelli, EPA*

- Satellite Imagery QA Concerns (G. Brilis and R. Lunetta, EPA)

Information Quality Perspectives (IQP) (Salons F-H) *Chair: J. Worthington, EPA*

- A Body of Knowledge for Information and Data Quality (J. Worthington, L. Romero Cedeno, EPA)
- Information as an Environmental Technology – Approaching Quality from a Different Angle (K. Hull, Neptune and Co.)

To Detect or Not Detect—What Is the Answer? (TDND) (Salon E) *Chair: A. Pitchford, EPA, Co-Chair: W. Puckett, EPA*

- Using Small Area Analysis Statistics to Estimate Asthma Prevalence in Census Tracts from the National Health Interview Survey (T. Brody, EPA)
- Logistical Regression and QLIM Using SAS Software (J. Bander, SAS)
- Bayesian Estimation of the Mean in the Presence of Nondetects (A. Khago, University of Nevada)

Ambient Air Workgroup Meeting (Sierra 5&6) *Contact: Mike Papp, EPA*
NOTE: This is an all-day, closed meeting.

10:30 – 12:00 THURSDAY, APRIL 14TH

Environmental Data Quality (EDQ) (Salons A-C) *Chair: V. Holloman, EPA*

- Assessing Environmental Data Using External Calibration Procedures (Y. Yang, CSC)
- Groundwater Well Design Affects Data Representativeness: A Case Study on Organotins (E. Popek, Weston Solutions)

Information Quality and Policy Frameworks (IQPF) (Salons F-H) *Chair: L. Doucet, EPA*

- Modeling Quality Management System Practices to an Organization's Performance Measures (J. Worthington, L. Romero Cedeño, EPA)
- Development of a QAPP for Agency's Portal (K. Orr, EPA)
- Discussion of Drivers and Emerging Issues, Including IT, That May Result in Revisions to EPA's Quality Order and Manual (R. Shafer, EPA)

Office of Water; Current Initiatives (OW) (Salon D) *Chair: D. Sims, EPA*

- Whole Effluent Toxicity--The Role of QA in Litigation (M. Kelly, EPA, H. McCarty, CSC)
- Review of Data from Method Validation Studies: Ensuring Results Are Useful Without Putting the Cart Before the Horse (W. Telliard, EPA, H. McCarty, CSC)
- Detection and Quantitation Concepts: Where Are We Now? (Telliard, Kelly, and McCarty)

Sampling Inside, Outside, and Under (SIOU) (Salon E) *Chair: J. Warren, EPA*

- VSP Software: Designs and Data Analyses for Sampling – Contaminated Buildings (B. Pulsipher, J. Wilson, Pacific Northwest National Laboratory , R. O. Gilbert)
- Incorporating Statistical Analysis for Site Assessment into a Geographic Information System (D. Reichhardt, MSE Technology Applications, Inc.)
- The OPP's Pesticide Data Program Environmental Indicator Project (P. Villanueva, EPA)

1:00 – 2:30 THURSDAY, APRIL 14TH

Information Management (Salons A-C) *Chair: C. Thoma, EPA*

- Achieve Information Management Objectives by Building and Implementing a Data Quality Strategy (F. Dravis, Firstlogic)

UFP Implementation (Salon D) *Chair: D. Sims, EPA*

- Implementing the Products of the Intergovernmental DQ Task Force: The UFP QAPP (R. Runyon, M. Carter, EPA)
- Measuring Performance: The UFP QAPP Manual (M. Carter, EPA, C. Rastatter, VERSAR)

Quality Systems Guidance and Training Developments (QSG) (Salons F-H) *Chair: M. Kantz, EPA*

- A Sampling and Analysis Plan Guidance for Wetlands Projects (D. Taylor, EPA)
- My Top Ten List of Important Things I Do as an EPA QA and Records Manager (T. Hughes, EPA)
- I'm Here---I'm Free----Use Me! Use Me!—Secondary Use of Data in Your Quality System (M. Kantz, EPA)

Innovative Environmental Analyses (IEA) (Salon E) *Chair: M. Conomos, EPA*

- Evaluation of Replication Methods between NHANES 1999-2000 and NHANES 2001-2002 (H. Allender, EPA)
- Assessment of the Relative Importance of the CrEAM Model's Metrics (A. Lubin, L. Lehrman, and M. White, EPA)
- Statistical Evaluation Plans for Compliance Monitoring Programs (R. Ellgas, Shaw Environmental, Inc.; J. Shaw, EMCON/OWT, Inc.)

Ethics in Environmental Operations – Its More Than Just Lab Data

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Abstract

The need for ethics in environmental operations cannot be underestimated due to the very nature of environmental work. It is costly, it cannot generally be repeated, and human health and protection of the environment are at stake. Therefore any type or incidence of fraud or misconduct in any area, including but not limited to laboratory data, can have a serious negative impact on environmental operations and all associated decision-making. Laboratory fraud has had devastating consequences on environmental data and the trust of environmental laboratories. The recent emphasis by the EPA and other organizations such as ACIL, NELAC and IFIA on ethics and data integrity in laboratory operations brings attention to the need for ethical conduct in the generation of laboratory data of known and documented quality with full integrity and authenticity.

In addition to laboratory data, there other significant issues to address in ensuring the overall ethics of an environmental operation. These include, but are not limited to, personnel qualifications, project costs, transparency of information, commitment on communications, mail and wire communications, responsibility for records retention and accessibility, financial reporting and honesty in all matters including unpleasant or undesirable information (such as lateness or errors.) For example, personnel qualifications must be correctly presented and not exaggerated or falsified (e.g., resumes, transcripts, employment applications); labor and expense costs must be true without falsifications (e.g., timesheets, expense reports); there must be transparency in disclosure of all required information and any relevant information must not be manipulated or withheld; verbal and written commitments must be followed through on without lack of compliance to commitments; all written communications (mail and wire transmissions) must be based on authentic information that has not been modified; and finally, since EPA has estimated that much of the error in environmental measurements is due to sampling, ethics practices must be followed in the field and in the associated collection, labeling, control and release of samples.

Background

In the 1980s, it was determined that many laboratories in the U.S. Environmental Protection Agency (EPA) Contract Laboratory Program (CLP) were committing fraud in order to be cost competitive and meet time demands of the CLP program. At one time, it was estimated that more than 25% of the laboratories in the CLP program were under investigation for fraud. The EPA began focusing on investigating laboratories as well as protecting the environment. In 1991, J. Worthington and R. Haney presented concerns about data authenticity and integrity in environmental laboratories.[1,2] Laboratory fraud continued to occur in the 1990s. Laboratories that were convicted were forced to close and/or pay high fines and penalties, and convicted personnel were required to serve time in prison or on probation and pay significant fines. Environmental data generated by laboratories that practiced fraud were deemed unreliable, thus causing large amounts of rejected data and repeated work, major delays in projects, and negative

impacts on all decisions made based on the data. EPA Region 9 reported in 1996 that laboratory fraud cost more than $11 million to taxpayers for mistakes in cleaning up contaminated sites.[3] The magnitude of the fraudulent data generated by environmental laboratories and the impact of that data on regulatory agency decisions and environmental cleanups was immeasurable. In response to these problems, the National Environmental Laboratory Accreditation Conference (NELAC) included ethics and ethics training requirements in their 1999 standard. This standard required labs to have an ethics policy statement and processes/procedures for educating and training personnel in their ethical and legal responsibilities including the potential punishments and penalties for improper, unethical and illegal actions. Similarly, in June 1999, the Americas Committee of the International Federation of Inspection Agencies (IFIA), which includes petroleum testing laboratories that perform tests on reformulated gasoline under the Clean Air Act, required that members have a regulatory compliance program to ensure ethical behavior and prevent fraud.

The author recognized that laboratories were in serious need of guidance in implementing ethics programs and developed a model for ethics programs in 1999 that has been described in several publications and presentations and has been utilized by many companies and organizations including the U.S. EPA.[4-8]. J.A. Boyd has also presented excellent guidance for ethics in the laboratory in several publications.[10-11]

Why Do We Need Ethics?

The U.S. EPA's Inspector General's Office has identified serious concerns about the ethics of environmental labs and has taken a very aggressive enforcement initiative aimed at identifying and prosecuting fraud. The Inspector General's Office has stated that a key element in preventing fraud is an organization's adoption of an ethics policy that is strictly enforced.[9] This means that it is not enough to just have an ethics policy, a laboratory has to communicate the policy and enforce it. A related white paper on fraud indicated that the biggest factor in preventing fraud is emphasizing a company's culture of integrity, i.e., commitment to ethical conduct. NELAC now requires a data integrity program and associated training as part of the quality systems requirement for lab certification. ACIL's Environmental Laboratory Data Integrity Initiative (ELDII) recommends that laboratory owners and managers implement an effective ethics training program to ensure data integrity and to avoid serious liabilities from fraud.

There is growing attention to ethics and the need for ethics programs in the corporate world, as well as in government. The Ethics Resource Center of Washington D.C. found in a recent survey that the number of firms with corporate ethics programs has increased from 7% in the 1980s to 40% since 1994, and that the number of companies with ethics codes has risen from 13% to 73% over that same period. President George W. Bush emphasized the need for ethics and maintaining the highest standards of integrity in his initial communication with his staff and Federal workers. Further, the Sarbanes-Oxley Act of 2002 addresses the need for accurate financial accounting and disclosure information which currently applies to publicly held companies and may be expanded to include other organizations.

The Complete Guide to Ethics Management – On-line Tool Kit by Dr. Carter McNamara (www.mapnp.org/library/ethics/ethxgde.htm) includes a positive summary of the benefits of ethics programs:

1. Improves society and employees' work lives
2. Provides moral compass in changing times
3. Promotes teamwork and increases productivity
4. Lowers employee stress and improves health
5. Insurance policy – cheaper than litigation
6. Helps prevent criminal acts and allows reduced fines
7. Assists other management programs (quality, human resources, tax, accounting, etc.)
8. Promotes strong public image
9. Improves customer trust
10. It's the right thing to do!

Plus it will help you sleep better at night.

Doug Wallace of the Twin Cities-based Fulcrum Consulting Group observes the following noteworthy characteristics of a high integrity organization that are applicable to environmental organizations:

1. There exists a clear vision and picture of integrity throughout the organization.
2. The vision is owned and embodied by top management, over time.
3. The reward system is aligned with the vision of integrity.
4. Policies and practices of the organization are aligned with the vision; no mixed messages.
5. It is understood that every significant management decision has ethical value dimensions.
6. Everyone is expected to work through conflicting-stakeholder value perspectives.

Standards for Ethical Conduct

Standards for ethical conduct are defined in professional organizations such as the American Chemical Society (www.chemistry.org/portal/a/c/s/1/acsdisplay.html?DOC=membership%5Ccode.html), the American Institute of Chemists (www.theaic.org/AIC2001/Ethics_.pdf), the American Society for Quality (www.asq.org/join/about/ethics.html), and the American Council of Independent Laboratories (www.acil.org/displaycommon.cfm?an=17). These standards address professional obligations and the need for independence, honesty and integrity in business conduct.

Specific standards for ethics and data integrity are found in the requirements or policies and procedures of the following organizations.

A. National Environmental Laboratory Accreditation Conference – Data Integrity Procedures (http://www.epa.gov/nerlesd1/land-sci/nelac/2002standards.html)

5.4.2.6 – Data Integrity System in Quality Manual

- Data integrity training
- Signed data integrity documentation for all laboratory employees

- In-depth, periodic monitoring of data integrity
- Data integrity procedure documentation

5.4.2.6.1 - Confidential reporting procedure for data integrity issues

5.4.2.6.2 - Communication to management on need for further investigation on ethics concerns

5.5.2.7 – Data Integrity Training

- New employee orientation and on an annual basis
- Signed data integrity documentation for all employees
- In-depth, periodic monitoring of data integrity
- Data integrity procedure

5.4.15 – Data Integrity Control and Documentation

- Include data integrity review in internal audit program
- Handle discovery process of potential issues in a confidential manner
- Document all investigations, findings, disciplinary action, corrective action and client notification
- Maintain documentation for a minimum of 5 years

B. American Council of Independent Laboratories – Data Integrity Initiative Essentials
(http://www.acil.org/associations/1304/files/ELDII%20Guidance%20Document%20Oct.%202003.DOC)

1. Business Ethics and Data Integrity Policy
2. Appointment of an Ethics and Compliance Officer
3. Ethics and Technical Training Program
4. Commitment to Effective Enforcement of Self-Governance Program
5. Policy for Internal Investigations and Reporting of Alleged Misconduct
6. Procedures for Data Recall
7. Effective Internal and External Monitoring System

C. International Federation of Inspections Agencies (IFIA) – Compliance Code Principles
(http://www.ifia-federation.org/contents4.htm)

Ms. Rosecrance was a member of the IFIA Compliance Committee responsible for developing the following compliance code principles:

1. Integrity
    a. Carry out work in a professional, independent and impartial manner.
    b. Perform work honestly, including reporting of accurate results with no deviations from approved methods and procedures.
    c. Reports shall present actual findings, professional opinions or results obtained.
    d. All information shall be treated confidentially, as appropriate.
2. Anti-bribery
    a. Prohibit the offers or acceptance of bribes, including kickbacks, in any form for contract payment.
    b. Prohibit receipt of improper benefits from customers, contractors or suppliers.
3. Fair Marketing

a. Conduct marketing in a truthful, non-deceptive or misleading way.
b. Present self in a fair manner.
c. Ensure that information presented is accurate and unambiguous.

D. International Federation of Inspections Agencies, Americas Committee – Regulatory Compliance Program (www.ifia-ac.org)

This program was developed in response to concerns about testing and reporting of reformulated gasoline under the Clean Air Act, and requires that members meet the following minimum elements.

- Ethics Statement
- Compliance Officer
- Compliance audits
- Compliance training
- Self-policing
- Zero tolerance

E. Core Laboratories – Ethics Program (www.corelab.com)

Ms. Rosecrance was the first Compliance Officer for Core Laboratories from 1998-2003 and was instrumental in developing their ethics program, which includes the following key elements:

- Company-wide Ethics Program and Policy
- Employee Ethics Agreement
- Full time Compliance Officer
- 24-7 Helpline
- Ethics Policy and Helpline Posters at each office
- Employee ethics information brochures
- Guide for Making Ethical Decisions and Ethics Do's and Don'ts
- Zero tolerance on unethical conduct
- Completion of Reportable Transaction and Conflict of Interest Questionnaire every two years

Examples of Unethical Laboratory Conduct

In addition to communication on general expectations for ethical conduct, it is important to inform laboratory personnel on areas that are not acceptable or not permissible, in case they are not aware of what is not allowed or if they have been misinformed in a previous position(s). The following are examples of what would be considered unethical laboratory conduct, subject to disciplinary action.

- Changing the computer date/time to meet holding times or calibration windows (time traveling)
- Using manual integration to inappropriately manipulate peak areas or heights to force them to meet calibration criteria (peak shaving or enhancing).
- Spiking samples with additional solutions or after the preparation to force recoveries to match QC requirements.
- Reporting data without actually performing the test (dry labbing).

- Using previous calibration data by changing date and running with new samples (file substitution)
- Deletion or removal of data qualifiers or flags (such as "m" for manual integration)
- Performing required procedures after tests are run to meet missed requirements.
- Deliberate lack of adherence to method requirement to force data to meet QC criteria.
- Changing or adding information to data after the fact without a valid reason.
- Using known expired standards or reference materials.
- Knowingly omitting information from a report or case narrative that may compromise the data.
- Not including known deviations or problems encountered in sample preparation and analysis.

Examples of Ethics Training

The following are examples of ethics training programs, geared at detecting and preventing improper laboratory practices.

- EPA – Detecting Improper Laboratory Practices (www.epa.gov/quality/trcourse.html)
- Joe Solsky, U.S. Army Corps of Engineers – Questionable Practices in the Laboratory
- New York Association of Approved Environmental Labs (www.nyaael.org./events-seminars.htm)
- Advanced Systems, Inc. – Preventing Improper Laboratory Practices
- Yield Education – Ethics with Integrity: The Foundations of Environmental Lab Excellence
- Analytical Quality Associates is developing web-based seminars (webinars) for ethics and NELAC preparation training.

Ethics in Personal Accountability

If everything you do is ethical, then it would follow that your data would be ethical as well. The following areas should be accurate and in accordance with professional standards of conduct.

- Resume – should reflect actual education, experience and qualifications and not include exaggerated or fabricated information.
- Timesheets – should reflect actual time worked.
- Expense reports – should reflect actual expenses related to business activities.
- Logbooks – should reflect actual observations and measurements, with any problems indicated.
- Computer entries – should reflect actual values and results obtained, with as many checks as possible to ensure accuracy of entered information.
- Sampling reports – should accurately report the sampling event and associated data/information.
- Laboratory data reports – should accurately report the tests performed, data obtained and any deviations, QC outliers or problems encountered.
- Invoices – should accurately reflect the work performed.
- Managers – should practice what they preach and be monitored for ethics compliance.

- Follow through on your commitments to others – Do what you say you are going to do.

By focusing on ethics in all areas of environmental operations, that include but are not limited to only laboratory data, the resulting work will be trusted and reliable. Ethics is demonstrated through action, and by recognizing and abiding by the highest standards of personal conduct, we do the right thing and demonstrate personal ethics.[12]

Ethics concerns in environmental operations include but are not limited to accuracy in personnel qualifications and disclosures, reporting of project costs, transparency of information and decisions made, personal representations and communications, accuracy and traceability of all information, as well as ethics considerations for field sampling and laboratory testing. By addressing more than just data in considering ethics for environmental operations and following ethics standards in all areas, better environmental management decisions can be made because all aspects and parties that contribute to those decisions can be respected and trusted. And thus the overall goal of protecting human health and environmental protection can be better ensured.

References

1. Worthington, J.C., and Haney, R.P., "Data Authenticity and Data Integrity: Essential Concerns for the Environmental Laboratory", American Environmental Laboratory Magazine, December 1991.

2. Worthington, J.C., & Haney, R.P., "Ensuring Data Authenticity in Environmental Laboratories" Proceedings of the EPA Seventh Annual Waste Testing and Quality Assurance Symposium, Washington, D.C., July 1991.

3. EPA Region 9 – "Best Practices for the Detection and Deterrence of Laboratory Fraud", California Military Environmental Coordination Committee, Chemical Data Quality/Cost Reduction Process Action Team, March 1997.

4. EPA Office of Inspector General, "Annual Superfund Report to the Congress for Fiscal 1999", Section on Assistance to EPA Management, Laboratory Fraud: Deterrence and Detection May 2000.

5. Rosecrance, A.E., "The Role of a Compliance Program and Data Quality Review Procedure" Proceedings of the Fifteenth Annual Waste Testing and Quality Assurance Symposium, Arlington, VA, July 1999.

6. Rosecrance, A.E., "Assuring Quality in the Lab – The Role of an Ethics Program and Data Quality Review Procedure," *Environmental Testing & Analysis*, Vol. 8, No. 5, September/October 1999.

7. Rosecrance, A.E., "Ethics Education Missing from Testing Laboratories," *SOLUTIONS*, Vol. 7, No. August/September 2000.

8. Rosecrance, A.E., "Ethics Education and Practices in the Laboratory," Proceedings of the 224th American Chemical Society National Meeting, Symposium on Principles of Environmental Sampling and Analysis – Two Decades Later, Boston, MA, August 2002.

9. Rosecrance, A.E., "Ethics Lessons Learned and the Role of Ethics in the Prevention of Fraud," Proceedings of the National Environmental Monitoring Conference, Arlington, VA, July 2003.

10. Boyd, J.A., "Defensibility and Ethics in the Laboratory," Quality Assurance J 2003; 7,79-83.

11. Boyd, J.A., "Scientific Ethics" Society for Quality Assurance Conference, February 2005.

12. Faggioli, V.J., "Ethics Training: Why Bother?" The Pacific Connection, U.S. Army Corps of Engineers, Honolulu Engineer District, October/November 2001.

Cooperative Research: "Ecological Monitoring and Assessment of the Great Rivers Ecosystem in the Central Basin of the United States" EMAP-GRE

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24th Annual National Conference on Managing Environmental Quality Systems

April 11-14, 2005

NHEERL, Mid-Continent Ecology Division

Environmental Monitoring and Assessment Program for Great Rivers Ecosystems (EMAP-GRE)

EPA Technical Director: Dave Bolgrien, Research Biologist

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WHY "EMAP-GRE?"

Following EMAP Research Strategy (USEPA 2002)

- Use probability based designs and indicators of biological integrity to make statistically defensible and policy relevant statements about aquatic resources.
- Condition reports are the first step in the assessment; it is necessary to understand current conditions to fulfill regulatory requirements.
- States and tribes could use these methods to estimate current ecological condition of all aquatic resources.
- These methods have not previously been applied to large floodplain rivers (GRE) - Mississippi, Missouri, and Ohio Rivers.
- Sampling designs and indicators to assess large rivers are not well developed and large rivers are difficult to sample.
- These large floodplain rivers have the highest discharges and watershed areas, are critical to receiving waters, and directly impact ecological condition in marine coastal systems.

THE MISSION - TO DEVELOP AND DEMONSTRATE THE MONITORING TOOLS NECESSARY TO ASSESS THE ECOLOGICAL CONDITION OF OUR NATION'S AQUATIC RESOURCES AND TO FULFILL THE REQUIREMENTS OF THE CLEAN WATER ACT IN A COST EFFICIENT MANNER.

Under MED Leadership

- Build on experience from Pilot Studies conducted on the Upper Missouri River, Coastal Assessment Program, and previous EMAP Projects.

- Ensure that planning is comprehensive with documentation to cover every step and in cooperation with state, federal, and interstate agencies experienced with river monitoring and assessment.

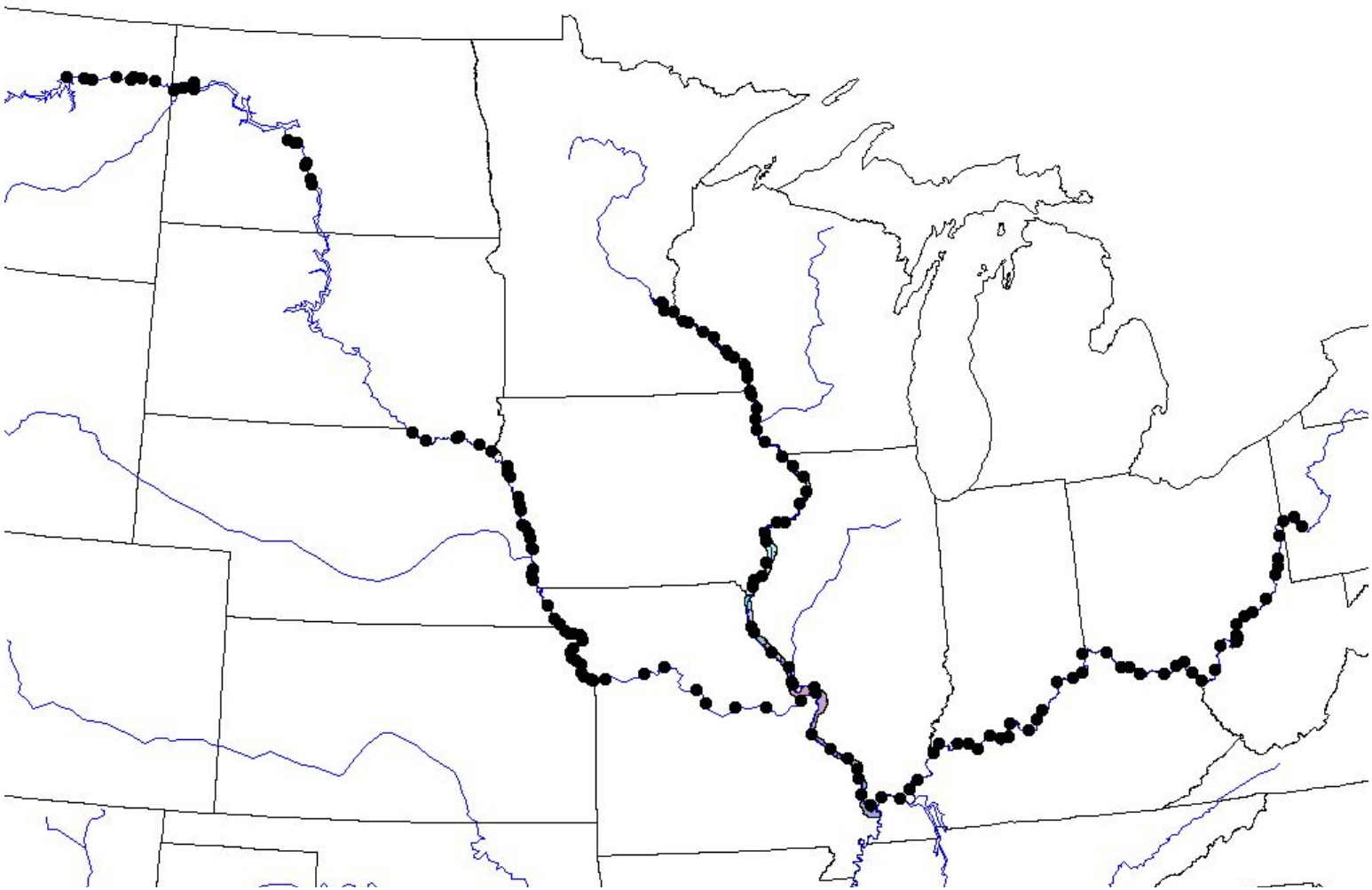
- Use Contracts, IAGs, and Cooperative Agreements as tools to develop partnerships to gather the required information on the rivers.

EMAP-GRE Documentation
(At Start of Research)

- EMAP-GRE Research Plan – 24 pages
- Field Operations Manual – 210 pages
  (Note: this is the working document for all field crews.)
- Quality Assurance Project Plan – 43 pages
- Field Safety Plan – 6 pages
- Animal Care and Use Plan – 10 pages
- OP Macroinvertebrate Laboratory Processing – 25 pages
- OP Sediment Toxicity Analyses – 57 pages
- PMP (USGS) Analysis of Fish Tissue Contamination – 15 pages
- OP Analyses of Sediment Enzyme Activity – 8 pages
- Grant Analysis of Periphyton and Phytoplankton for EMAP-GRE – 14 pages
- OP for Analyses of Elemental and Stable Isotopes of Total Suspended Solids and Particulate Organic Matter – 9 pages
- OP Analysis of Zooplankton – 7 pages
- Provisional EMAP-GRE Data Use Guidelines – 1 page

Scope of the Great Rivers EMAP

(Missouri River Reservoirs sampled under the Upper Missouri River Research Plan, which developed techniques used in this plan)



What is the goal?

To test monitoring methods that are more economical while maintaining scientific validity.

The ultimate measure of program success will be to have the approaches adopted by state and federal managers who conduct routine monitoring and assessment.

Great Rivers EMAP Organization

MED has Overall Leadership at all stages

EPA ORD NHEERL Director
Associate Director for Ecology
EMAP Director

MED (Duluth) Division Director

Technical Lead

Management Team	
Project Administration	**Quality Assurance**
Health & Safety	**Extramural Funding**

Science Teams	
Sample Design	**Methods/ Training**
Information Management	**Data Analysis / Assessment**

Partners

Upper Missouri River	Lower Missouri River	Upper Mississippi River	Ohio River	Analyses
-EPA Region 8 -Fort Peck Tribe -USGS in ND & Montana -ND Dept Health	-EPA Region 7 -USGS in Missouri, Iowa, Kansas, Nebraska -Missouri Dept of Conservation -Nebraska Game & Fish Commission -University of Iowa	-EPA Region 5 -USGS Upper Midwest Environmental Sciences Center -Wisconsin DNR -Minnesota DNR -Iowa DNR -Illinois Natural History Survey -Missouri Dept of Conservation	-EPA NERL -EPA Region 3 -EPA Region 5 -ORSANCO -SoBran Inc	-University of Louisville -Stroud Water Center, SW Missouri State University -USGS UMESC -EPA NERL,SoBran Inc. -EPA NHEERL, Wilson Env. Labs

Cooperator Breakdown

Inter Agency Agreements (IAG)

- Field Crews
  - USGS - 4
  - State under USGS Funding – 6+**(some assistance to USGS Crews via IAG Funding)**
- Analytical Laboratories – 6 (federal, state, and private)

Contracts - 2

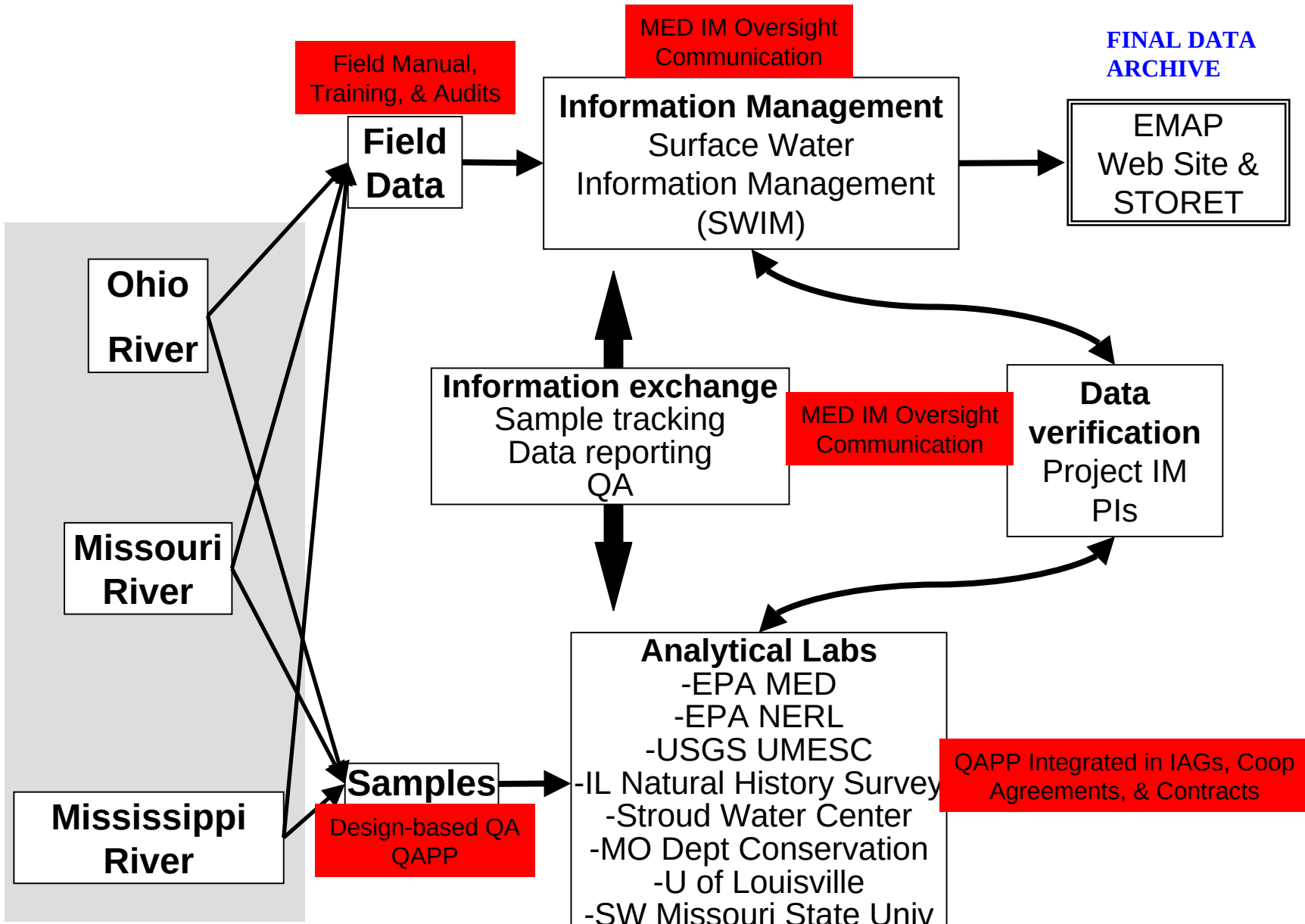
- NERL – SoBran, Inc.- Field and Analytical Support
- NHEERL, MED – Wilson Environmental Lab - Tax.

Grants

- River Monitoring – direct to GRE states (17 potential)
- Periphyton Analysis – (RFP)1

18 different organizations are participating in this Research Plan.

Laboratory and Information Management QA Basics



Headlines from the EMAP-GRE Program

PLANNING DOCUMENTS

- Approved Research Plan and QAPP
- Collaborations result in 225 page Field Operations Manual (FOM)
- Multiple Analytical Labs Submit OPs
- EMAP-GRE Newsletter produced starting in March 2005 to highlight program activity and challenges

TRAINING, PLANNING, AND DEBRIEFING

- Four 3-day sessions train 85 people from 9 agencies
- Post-season debriefing teleconference sessions conducted
- Post -season Technical Meeting to discuss all points necessary for completion of the research

INTERNAL MEETINGS

- On-going weekly Principal Leaders Meetings held to discuss program activity and events

INFORMATION MANAGEMENT

- All-hands emails keep crews informed, provide FOM corrections/alerts
- Web-based Sample Tracking System implemented -
  - Surface Water Information Management Systems (SWIMS) used by other EMAP projects
  - Provisional EMAP-GRE Data Use Guidelines

FIELD AUDITS

- Field Audits completed for all crews
- Audit revealed -
  - Wrong bank sampled, crew re-sampling site. Site layout rules reviewed.
  - Duplicate Sample IDs found in database, obsolete labels identified and removed.
  - Inadequate Fish Vouchers collected, crews to increase photo or specimen vouchers.
  - Confusion over landcover classes, glossary added to Manual.

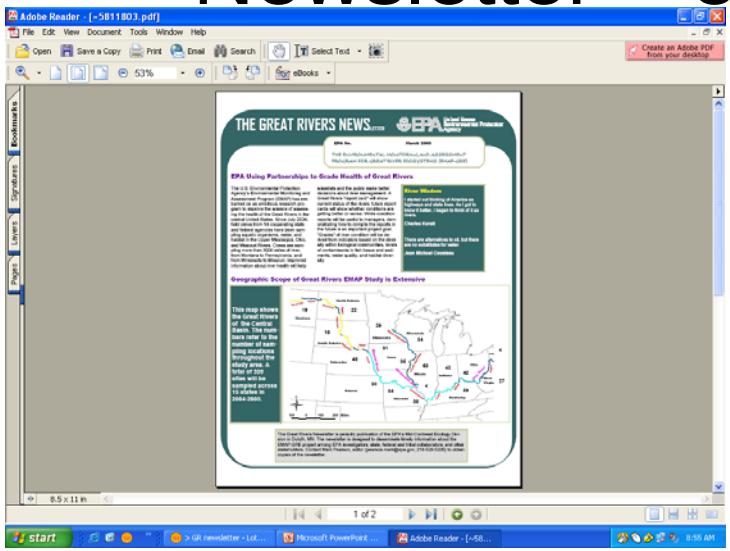
- Lab Audits to be completed

The EMAP-GRE Program

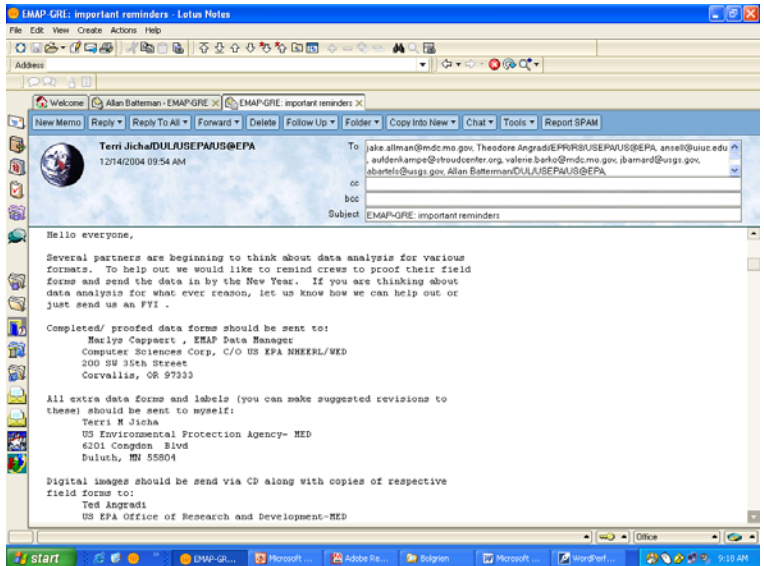
Design-based QA Requirements	*Field Operations Manual*	*Information Management*	*Communication*	*Field Training*	*Field Audits*
20% site re-visits by river	Single authoritative source.	Single source of forms and labels	"All-hands" email alerts to crews	Hands-on and realistic	Face-to-face visit with each crew while sampling
10% duplicate and blank samples by crew	Used in training	Tracks samples	Logs decisions made and corrective actions	Include all procedures and forms	
	Written with partners	Accessible to crews and labs	End-of-season debriefing	Time for practice	Crew-specific corrective actions
	Updates tracked		Conference calls	Review of site dossiers	As needed, all-hands emails
	Contains all standard forms and labels		Technical Committee Meetings		
			Newsletter		

Communications

Newsletter – e-mail distribution



E-mail Notification of Concerns –



What is the current focus?

- Program Objectives
- Field Data Collection (2004-2005)
- General Strategy
- SWIMS Data Base fields – 2004 Field Data Verification
  On-going
- Are we gathering information so that it can be easily searched and cross referenced ?
- Was training adequate ?
- Lessons learned ?
- From results obtained in the first season, does the Field Operations Manual need to be modified ?

Further Information ?

How do I get on the e-mail list for the Newsletter ? Contact Pearson.mark@epa.gov

How do I get a copy of the Field Operations Manual or any other planning document?

Contact Batterman.allan@epa.gov

Any Questions ?

The United States Environmental Protection Agency
24th Annual National Conference on Managing Environmental Quality Systems

Dealing with Fishy Data: A Look at Quality Management for the Great Lakes Fish Monitoring Program

Elizabeth Murphy[1], U.S. Environmental Protection Agency, Great Lakes National Program Office, 77 West Jackson Boulevard, Chicago, Illinois 60604, Judy Schofield[1], Ken Miller, and Harry McCarty, Computer Sciences Corporation, 6101 Stevenson Avenue, Alexandria, VA 22304

The Great Lakes National Program Office is currently implementing the Great Lakes Fish Monitoring Program (GLFMP) in cooperation with the Great Lakes States, selected State agencies, and Native American Tribes. The program involves assessment of a variety of contaminants in game and predatory fish collected from the five Great Lakes. Game fish include Coho and Chinook salmon in Lakes Michigan, Superior, Ontario, and Huron and rainbow trout in Lake Erie. Predatory fish include lake trout in Lakes Michigan, Superior, Ontario, and Huron, and walleye in Lake Erie. The current list of analytes of interest consists of a wide variety of organic contaminants and mercury, a metal contaminant of specific concern in the Great Lakes.

The overall goals of the GLFMP include:

- Monitoring temporal trends in bioaccumulative organic chemicals in the Great Lakes using top predator fish as biomonitors,
- Assessing potential human exposure to organic contaminants found in these fish, and
- Providing information on new compounds of concern entering the lakes ecosystem.

GLNPO has developed an extensive quality management program for the fish monitoring effort. The program involves quality assurance project plans, standard operating procedures for both sampling and analysis, standardized field information recording forms, laboratory audits, a detailed data reporting format, data verification, and data quality assessments. In addition, rigorous laboratory quality control procedures are implemented and involve preparation and analysis of surrogate spikes, laboratory duplicates, and analytical blanks.

The quality control data generated in the study are used to develop quantitative data quality assessments. These assessments are determined for each target analyte included in the study for each year's data. Estimates for sensitivity, precision, and bias are calculated based on the pooled results of the quality control samples. The data quality assessments aid in the identification of data quality issues for each target analyte and provide a measure of the potential impacts on the utility of the data in GLFMP decisions. These assessments are one of many tools used in ongoing evaluation of the program.

[1]Presenters

Development of a Quality Assurance Program for the State of California Surface Waters Ambient Monitoring Program

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Abstract

The State of California's Surface Water Ambient Monitoring Program (SWAMP) used a progressive approach to develop its quality assurance (QA) program. California's size and varied water bodies presented SWAMP special considerations and obstacles to the traditional method of QA. SWAMP is administered by the California State Water Resources Control Board with implementation of monitoring activities carried out by the state's nine Regional Water Quality Control Boards. Other organizations involved include the California Department of Fish and Game, the US Geological Survey, and the Moss Landing Marine Laboratory's Data Management Team. In development and design of a QA program all organizations need to be satisfied even if goals and means differ. With the added burden of today's budgeting constraints, development of a standout QA program was challenging.

The SWAMP QA program utilizes many of the traditional QA elements, but it is how they are implemented, and the level of documentation, that is interesting and unique. The QA Team and SWAMP management created a flexible program allowing for varied method detection and reporting limits. They also implemented a website QA toolbox for participants to quickly access items such as boiler-plate contract language, standard operating procedures for data verification/validation, and a QA calendar of events. The QA Officer's role evolved into that of a consultant to the state's Regions and contract laboratories. For example, the QA Team brings together expert focus groups to evaluate new ideas for sample collection, analysis, and reporting. The QA Team also works one-on-one with contract laboratories to help write and refine standard operating procedures and create QA systems and documentation.

It was essential to develop a fluid QA program molded to the scientific needs and budgeting constraints as they might change. "Flexibility", "science-based decisions", and "application-appropriate data" are terms that entered SWAMP's daily vocabulary. A progressive QA program can cross the bounds from programmatic compliance into a philosophy embraced by all stakeholders. The SWAMP QA program was designed to satisfy a wide variety of stakeholders and produce excellent data.

Introduction

The SWAMP QA Officer developed a tool to help managers design a QA program that would fit into SWAMP's funding and provide rigorous QA. This tool allows the program to move flexibly as its overall scope or funding change. The QA Officer also worked closely with program management and the QA Team to create QA Team goals, values, and a vision for the future. Essential to these elements is the design and implementation of a series of systems in regard to each QA program component. The use of systems allows the program to easily modify itself and enables efficiency. The systems also outlive personal staff involvement in a project or program ensuring long-term success.

Funding and Design of a QA program (Flexibility)

The SWAMP QA program design process used a step-by-step approach in order to produce a QA program outline and a management tool. The management tool allows fast and easy refinement and revision of its QA program as overall SWAMP funding or its scope of work change. This is an essential and generally overlooked tool that QA professionals should always develop for program management.

Quality assurance components were presented to program management as a "QA Menu" with each component fleshed out in vast detail, step-by-step processes, approximate time commitments over 18 months, and projected budgetary requirements. The program must set up a series of systems for each QA component and therefore, costs of the program will vary as systems are set in place and maintained. The "menu" presented was a design for a stand-out QA program that would encompass all the QA components needed to place SWAMP in world-class standing. The purpose of the "QA Menu" is to begin a series of discussions between QA professionals and program management to assess funding possibilities and constraints, combinations of QA components suited to the program, long-term planning, and vision. The "menu" allows program management to come to the table well educated on the possibilities. Using the "menu" with the guidance of QA professionals, the program management may be walked through different scenarios and what those scenarios might achieve. It is this process that is vitally necessary given contemporary funding constraints and the sheer size of SWAMP.

In order to describe this process in an example, assume a program's total annual funding budget is $1,000,000. The program looks at tissues, sediments, and water samples for conventionals, inorganics, organics; it also examines toxicity testing in waters, conducts bioassessment studies and takes field measurements in waters. The program's data is uploaded onto a master database and could be utilized by any end-user group for the purposes of state listings, academic research, health advisories, remediation plans, environmental decision making, and many other areas. A fully funded QA program would be at 25% of the total programmatic costs, or $250,000 (Table 1).

Table 1. Example Exercise: Funding allocations for QA components in fully-funded program

Component	*Percentage of Funding*	*Funding Allocation*
Communication/Daily Management	4.8%	$12,000
Organizational Chart and Calendar	2.4%	$6,000
QA Reports to Management and Management Assessment	6%	$15,000
Quality Management Plan (and Regional QAPPs)	8%	$20,000
Data Review (verification and validation)	16%	$40,000
Intercomparison Studies/PE Studies/Inter-laboratory Precision	14%	$35,000
QA audits of research plans and sampling plans	8%	$20,000
On-site audits for analytical laboratories	7.2%	$18,000
Corrective Action File	2.4%	$6,000
MDL Studies	2%	$5,000
QC Sample Control Charts	4%	$10,000
SOP review and approval	4%	$10,000
On-site audits of field sampling	5.2%	$13,000
Expert Panel	8%	$20,000
QA Training and QA “toolbox” for SWAMPers	8%	$20,000
Total for Example Exercise	100%	$250,000

This breakdown allows program management to play with different ideas and combinations of components. The QA professionals can describe how best to interact QA components and what the different interactions will yield. It is important to note that the percentage projections for QA components are estimates for the first 18-24 months of large-scale programs.

For the SWAMP QA program, management allocated a 12% (of total program funding) budget. The QA professionals and program management worked through different scenarios and discussions about dropping whole QA components, or streamlining specific QA components. While it is the program’s long-term goal to encompass all the QA components, funding and efficiency demanded that components be addressed in phases rather than collectively.

Keeping with the above example program funded at $1,000,000, this means our 12% QA budget gives us $120,000 to work with. The program management and QA professionals honed the list of components down to the list shown below (Table 2). One point that must be remembered is that while QA program funding may go up or down as a percentage, the total program funding does not. Therefore, the total projected budget (versus its percentage) for each element remains static. QA component costs are directly related to size of the program.

Table 2. Example Exercise: Funding allocations exceeding 100% of available budget.

Component	*Percentage of Funding*	*Funding Allocation*
Communication/Daily Management	10%	$12,000
QA Reports to Management and Management Assessment	12.5%	$15,000
Quality Management Plan (and Regional QAPPs)	16.7%	$20,000
Data Review (verification and validation)	33.3%	$40,000
On-site audits of field sampling	10.8%	$13,000
QA Training and QA "toolbox" for SWAMPers	16.7%	$20,000
Organizational Chart and Calendar	5%	$6,000
Intercomparison Studies/PE Studies/Inter-laboratory Precision	29.2%	$35,000
On-site audits for analytical laboratories	15%	$18,000
Total for Example Exercise	149.2%	$179,000

It is obvious that our honed down list still was almost 50% higher than our budget would allow. The "QA Menu" was very helpful in assisting our decisions as to what and how to cut. Since the "menu" detailed each component, we were able to not only decide to remove more whole components, we were also able to revise some of the component details in order to retain the general component, or to phase in portions of the component over a longer term. The next list was the final SWAMP QA program outline for the first 12 months (Table 3 and Figure 1). Other elements and more details within certain components would be brought in over a 24 months period. In total, our goal was to keep all the components listed in the "QA Menu" within a 24 month period.

Table 3. Example Exercise: Appropriate funding allocations for a customized program.

Component	*Funding Allocation*
Communication/Daily Management	$6,000
Organizational Chart and Calendar	$6,000
Quality Management Plan (and Regional QAPPs)	$20,000
Data Review (verification and validation)	$35,000
Intercomparison Studies/PE Studies/Inter-laboratory Precision	$10,000
On-site audits for analytical laboratories	$18,000
On-site audits of field sampling	$13,000
QA Training and QA "toolbox" for SWAMPers	$12,000
Total for Example Exercise	$120,000

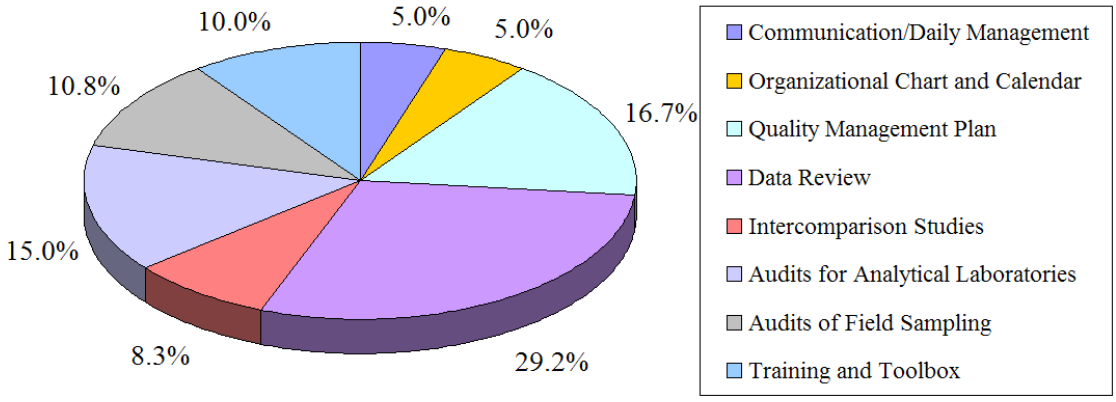

Figure 1. Appropriate funding allocations for a customized program.

After the basic program outline was established for the first 12 months, the QA program needed to develop goals, QA Team values, and a vision for the future. These aspects are usually absent from a QA program outside of data quality objectives (DQOs), but are vitally important not only for the success of the program, but for the morale of participants and the QA Team. Developing systems and implementing them effectively with a varied participant body can lead to burnout among QA professionals. Goals, values and a vision for the future can help the QA team get through the first 18 months of implementing a large-scale program. The SWAMP QA Team goals are to develop a progressive, innovatively cost-effective and well-defined program that is coherent and attractive to all stakeholders, retain a key focus on how to best serve dischargers and Regional Boards, and to provide new techniques for the QA profession and regulatory communities. The SWAMP QA Team values are to develop comparability between programs/projects in order to answer big-picture questions, to help the program create data that is defensible – data that is valid for future interpretation, to develop tools and systems to improve efficiency and that may be utilized by other programs/projects, and to remain sensitive to budget challenges with a creative approach to program requirements. The SWAMP QA Team's vision for the future is to develop and implement a large-scale QA program that will ensure data is suitable for our intended use, to show that quality assurance and its quality control requirements can save costs and produce data that is valid for future use and interpretation, and with a hope that the QA program will serve as a model for other programs and projects.

Varied Method Detection and Reporting Limits (Application-appropriate Data)

SWAMP incorporation of multiple Regions in one program produced a challenge during the DQO planning phase. The program faced questions about how to best mandate method detection limits (MDLs) and reporting limits (RLs). What would yield the most usable results? What were the questions we wanted to answer with this data? The data would need to answer questions at the local (Regional) and state level. A knee-jerk reaction might have been to mandate set MDLs and RLs. SWAMP required a system that could look beyond the traditional QA utilization of MDLs and RLs. SWAMP needed to create application-appropriate data in order to most efficiently utilize the tight budgets for sampling and analysis. The SWAMP QAMP DQOs did

mandate *target* MDLs and RLs that all projects within the program should strive to obtain. The limits are low due to some of the pristine waters in the state. The QA question that became obvious was: How does a program incorporate, accept and document variances to target MDLs and RLs so that data and decisions are later defensible?

The QA team developed a system for assessing higher MDLs and RLs on a case-by-case basis. If participants or projects within the program chose to meet the SWAMP QAMP target MDLs and RLs, then the SWAMP QAMP and DQOs only need to be referenced in the project-specific QA Project Plan. If the project desires to raise MDLs or RLs, then a system had to be created. The QA team answered this need and developed a standard operating procedure that details the how, why and what objective information must be presented for a variance to be granted. Some of the evidence given should address historical data, regulatory concerns, listing purposes, local or federal standards, and recent publications or academic research.

In order to illustrate this process, one may look at a recent example. The SWAMP target RL for nitrate (as N) in waters is 0.01 mg/L. One of the Regions requested raising the RL to 0.1 mg/L for an agricultural waiver program. The Regional representative wrote a 2-page memorandum to the SWAMP QA Officer and detailed points such as:

- A review of the historical data on nitrate from the initial working site list for the project showed that a RL of 0.1 mg/L would result in a total non-detected (below the MDL) or non-quantified (above the MDL but below the RL) rate of 3.6%. In addition, a review of the entire Regional database showed that a RL of 0.1 mg/L would results in a 14.7% non-quantified rate.

- For listing purposes, all of the sampling sites are located in water bodies that are currently listed on the 303(d) list for agricultural pollutants, are proposed for listing, or have groundwater basins that are impacted by nitrate, some of the water bodies routinely exceed the drinking water standard.

- In comparison, the municipal drinking water standard (10 mg/L as N) is 100-fold greater than the requested RL of 0.1 mg/L and EPA Region 9 has recommended that 1.0 mg/L be the level for water body listing of aquatic life impairment (10x higher than the requested RL).

- Finally, based on the supporting evidence, sites with concentrations at or below the requested RL would be considered in very good condition from the standpoint of nitrate.

The QA Officer responded with a written memorandum to the Regional board and the SWAMP Coordinator at the State Board recommending permission of the raised RL. The memorandums and supporting documents then are public for a period of two weeks to allow sufficient time for comment. In the example above, no comments came in and the variance was officially granted.

The SWAMP QA program's development of systems answered the questions posed above. In order to produce data that yields the most usable results, and that will answer questions at the local and state levels, the program required a system to produce application-appropriate data.

Creating a system that requires evidence and documents for each step and decision ensures our data will be defensible and valid for future interpretation.

QA Officer as Consultant (Science-based Decisions)

The QA Officer's position has evolved into a consulting role for the Regions and the contract laboratories. The QA Officer and QA Team work directly with labs before, during, and after laboratory audits to develop more rigorous and efficient quality systems. This process has the incidental benefit of ensuring that contract laboratories comply with all relevant SWAMP requirements.

However, the QA Team's close interaction with contract laboratories continues beyond the auditing process. Often, this open line of communication leads to instances where guidelines specified in the SWAMP QAMP can be amended or altered to more closely suit contract laboratories, either individually or collectively. The idea is to modify the QAMP to reflect cutting-edge science rather than using the QAMP to mandate protocols just for consistency. Too often, QA programs do not remain flexible to scientific discoveries as they become available. The SWAMP QA program and its QAMP are designed to allow fast change while retaining comparability of data over time. In such instances, this deviation must be documented and scientifically justified using a carefully-defined study. Already, the SWAMP QA Team has worked with its contract laboratories to examine QAMP guidelines pertaining to sample containers and sample extract holding times.

Recently, an environmental consulting firm suggested that one of the Regions change the type of its toxicity sample containers. The container type differed from the specified container in the SWAMP QAMP. The consulting firm then produced a study design to test the proposed container's suitability for toxicity testing. The Region did not have the expertise, or the tools to assess the study properly. In response, the SWAMP QA Team recruited world-known experts in various fields to assess the container study. The SWAMP QA Officer reviewed the study from a statistical and quality standpoint. An organics expert, an expert in container types for sampling toxicity, and a toxicity testing expert then contributed their technical assessment of the study. The QA Officer directed these experts to approach the study as if it were for peer-review in a journal. After each expert responded with questions and comments, the QA Officer combined all items into a formal memorandum that was issued to the Region. The study required significant changes to become acceptable and justify using its outcome. The memorandum spelled out the necessary steps to create a study that would meet publication requirements. The QA Team offered to work with the Region and the consulting firm in order to make the amended study a reality.

Program-mandated sample holding times are another issue of great importance to SWAMP contract laboratories. Holding times become the basis for many aspects of a method's protocols and scheduling. For example, the QA Team has learned that many contract laboratories specializing in organics analysis have a difficult time meeting holding times between sample extraction and analysis. Consequently, the QA Team is currently working with a SWAMP contract laboratory to examine the limits of this crucial time period. The study is being designed with publication (e.g., *The Analyst* or *Analytical Chemistry*) ultimately in mind. This way,

SWAMP's hold time protocols, as well as the industry standards on which they're based, can be established with a scientific and statistical basis. In some instances, this close interaction leads to instances where guidelines specified in the SWAMP QAMP can be altered to more closely suit cutting-edge science. In such instances, this deviation must be documented and scientifically justified through peer-review.

In the examples provided above, it is the QA program for SWAMP that directs changes to sampling, analysis, and reporting protocols. Through utilizing the centralized office of the QA Team, the program is able to quickly move on new findings and to do so in a manner that is technically defensible. Peer-review publication is always the standard used for SWAMP.

Data Verification and Validation (Creating a System)

After four years of collecting data, SWAMP needed a system for data verification and validation that was centralized and streamlines. While most programs do not require contract labs to follow a program-written and standardized operating procedure (SOP) for data handling, SWAMP was to become the model for efficiency and data quality. Furthermore, the sheer number of SWAMP contract laboratories and analytes required some degree of consistency among submitted data batches.

The QA team developed a rigorous SOP for contract labs to use and apply to data verification and validation prior to submittal to the SWAMP data management team (DMT). Data verification ensures that reported results accurately depict work performed by the contract laboratory. Data validation confirms that the verified data batch meets the overall quality requirements of the SWAMP project. Presenting these processes separately ensures that a data batch's usability is not considered until a standardized peer-review has occurred. With this SOP, the DMT is burdened with fewer unusable data batches, as these batches are now being identified and remediated at the contract lab level.

Given their active role, the data handling SOP was designed to be easily adopted by each of SWAMP's contract laboratories. Were this not the case, the SOP's use would decline, and the desired effect of consistency through standardization would be lost. The SOP is general in its scope and tone. This allows its guidelines to be applied to, and incorporated with, each contract laboratory's existing data handling protocols. All the while, the SOP strictly mandates adherence to the SWAMP Quality Assurance Management Plan (QAMP). This ensures that the QA Team's goal of flexibility does not come at the expense of overall program goals.

The ability to quickly review quality control parameters at a data batch level can be helpful in many instances throughout the reporting process such as data verification, QA review, and transfer of information to a database. A set of method-specific Quality Control (QC) check sheets were created to meet this need. The goal of the QC check sheet is to provide a format to compare the QC results of a data batch to the QC requirements of the SWAMP program and to provide a snapshot view of routine assessment of precision, accuracy, and contamination on a batch level.

The process begins with laboratories completing the tables on the QC check sheet prior to submitting EDDs (Electronic Data Deliverables) to the DMT for uploading to the database. Information to be entered on the sheets includes sampling date, preparation/analysis method and date, matrix spike and certified reference material recoveries replicate relative percent differences, and blank results. The tables also include method-specific DQOs and QC frequencies required by SWAMP, providing an efficient method to check the data batch for comparability with those parameters without having to refer to other documents.

The completed QC check sheet provides a tool for the laboratory to quickly review the data and ensure that the program's DQOs have been met. If they have not been met, the form provides a straightforward manner to distinguish which results require qualifier flags or re-analysis before submittal to the database. The QC check sheets can also be used by a project manager to document QC results from blind replicates or field blanks.

Upon receiving the EDD, members of the DMT are able to quickly spot any QC concerns in the data batch by reviewing the completed QC check sheet. For example, if the time period between the sample collection date and the extraction date exceeds the holding time listed on the check sheet, the DMT member can call the lab and check if there was a documentation error or if the data must be flagged before being entered in the database. This allows for efficient trouble shooting prior to data uploading and reduces the amount of time spent making corrections after the data is entered into the database.

In addition, the QC check sheets can streamline internal or external QA overview of the data batch. The reviewer can quickly observe any trends within a data batch such as a general high bias or contamination in the blanks before delving into the entire data set. The check sheets could also be used for insight into a problem. For instance, a review of multiple check sheets for the same method could show if a QC concern is a single occurrence or a recurring item. The check sheets could be used as part of an analyst's training record as documentation of ability to routinely perform a particular method, as well.

In addition to the systems developed for verification and validation by contract laboratories, the QA team and the DMT developed SOPs for data verification by the DMT and data validation by the QA Team. Therefore, SWAMP data undergoes a series of verification and validation checks to ensure that end users receive only high-quality or properly flagged data. This process (Figure 2) may appear to be labor-intensive, but has proven to ultimately save the program time and funding resources. The key to success with any data gathering program is to find problems and initiate corrective action steps in "real time".

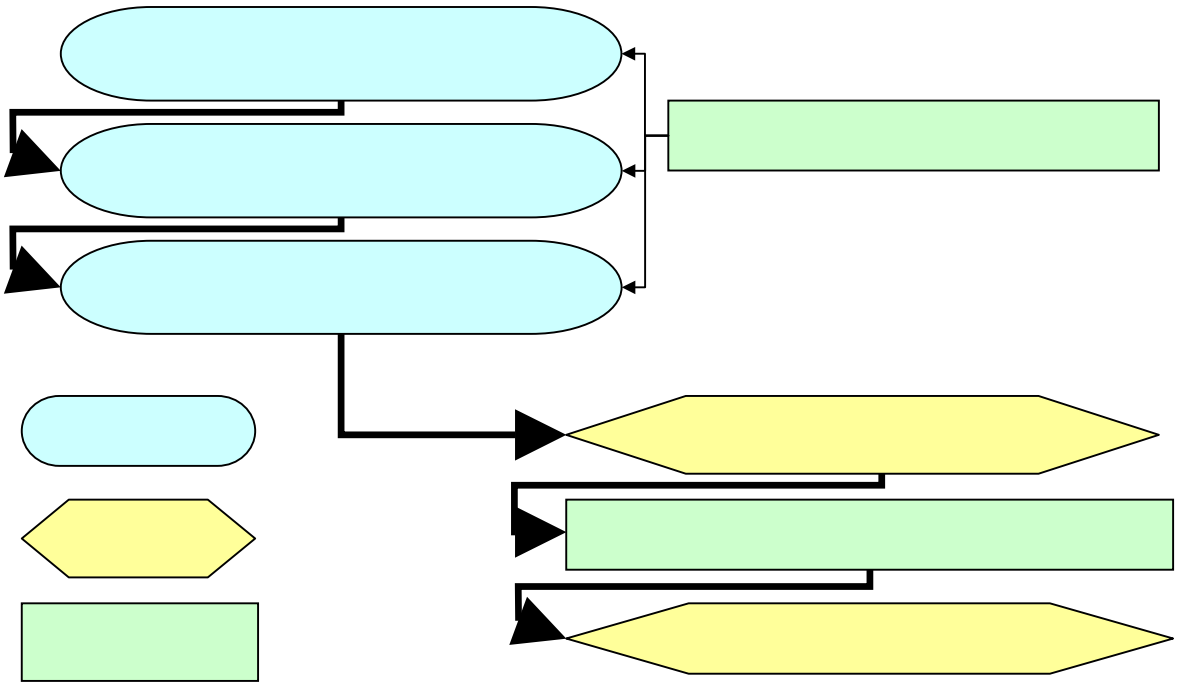

Figure 2. Flowchart of SWAMP Data Verificaiton and Validation Systems.

Conclusion

It was necessary to create long-term visions for each SWAMP QA component and realize how each component could be developed into a working system that would produce high efficiency and be easy to modify. The long-term vision allows the program to implement QA components in steps and over time in order to best utilize funding. Due to the large scale of the state of California, and its varied water bodies, the program faces many challenges in its DQO design. Bringing all of these aspects together creates a progressive QA program that can cross the bounds from programmatic compliance into a philosophy embraced by all stakeholders. The SWAMP QA program was designed to satisfy a wide variety of stakeholders and produce excellent data.

Acknowledgments

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References

Buuren, B.H. van, 2005, “The SWAMP QA Menu,” SWAMP Round Table Meeting, Rancho Cordova, CA.

Puckett, H.M. 2002, “Quality Assurance Management Plan for the State of California’s Surface Water Ambient Monitoring Program.” California State Water Resources Board.

SWAMP SOP 2005, “Surface Water Ambient Monitoring Program (SWAMP) QA Program Contract Laboratory Data Verification and Validation.” California State Water Resources Board.

SWAMP SOP 2005, “Surface Water Ambient Monitoring Program (SWAMP) QA Program On-site Systems Assessments of Contract Laboratories.” California State Water Resources Board.

Integrating EPA Quality System Requirements with Program Office Needs for a Practical Approach to Assuring Adequate Data Quality to Support Decision Making

We are looking at the quality assurance project plan development and approval process as an information system. An initial product will be a system flow chart to facilitate having the OEI Quality Staff and our OWM QA staff work together to design improvement to the process, which will reflect an integration of the Quality Staff's understanding of the EPA Quality System and our program office's understanding of what approaches will be effective as we apply the EPA Quality System to our OWM operating programs. Expected products include a final version of the flow chart that can be used to educate program office staff, a new environmental data review form, and improvements to other system outputs, e.g., QA Requirements Statement, QA Review Form, Work Assignment Checklist, QAPP, and QAPP Review Checklist. The presentation will emphasize how the system's improved architecture and outputs mutually reinforce one another, meet program office needs for a practical approach and comply with EPA's Quality System Requirements.

During our QSA last month, Gary Johnson and Espranza Renard reviewed drafts of the flow chart and new environmental data review form. You may want to ask them for their opinion of this proposal.

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Introducing Changes to Quality Systems in Large, Established Organizations

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To achieve the Environmental Protection Agency's (EPA) mission of having defensible and reliable scientific data with which to make informed decisions, the EPA Quality Assurance (QA) community must continue its successful efforts in increasing support for QA activities through personal communication and carefully planned outreach and training. This paper will present a case study involving planning and implementation of administrative changes to QA procedures within an established quality system. Topics discussed include the tendency of program groups within large organizations to isolate themselves, introducing and implementing change across organizational lines, considering stakeholder priorities, and suggested improvements to the way we have conducted QA business in the past so that we can make our programs more successful.

Introduction

Quality Assurance (QA) at EPA has undergone many changes in the last six years, and EPA QA personnel have been responsible for rolling out these changes to the people who will implement them in the course of their duties. Although management has been increasingly supportive, members of the QA community, themselves, have been the direct instruments of change, through continued communication with stakeholders. Because different organizations with varied functions, educational backgrounds, political climate, and cultural history require individualized approaches to implementing change, the efforts of various QA groups within EPA have met with varying degrees of success. The *intention* of our communications with other organizations is that new policies or procedures would be wholeheartedly adopted by our stakeholders who would then be able to knowledgeably carry them out without much oversight or assistance. With those intentions in mind, we should continue to examine areas of our programs and outreach that have room for improvement.

Over the last six years, the QA community has made significant headway in increasing management support at all levels for QA activities. At the 21st Annual EPA Conference on Managing Quality Systems in 2002, Wade Ponder, a manager in the Office of Research and Development, presented a paper[1] advocating that in order for a QA program to be successful, management must be committed to and supportive of QA. Essentially, if we do not have management's full buy-in that QA is an important value-added activity, the QA program will not be as successful as it should be. It speaks volumes that the QA community took considerable notice that a member of EPA management attended the conference and made a presentation. He represented the embodiment of our continued progress.

Until recently, the QA community has focused its outreach on members of EPA management. However, there are other stakeholder groups that have just as much impact on our daily activities. Stakeholder groups that QA personnel interact with on a routine basis include researchers, scientists, contracts and grants management staff, Contracting Officer's Representatives (CORs), contractors, and cooperators. While we can all agree that scientific data integrity is of utmost importance to enable the EPA to make reliable and defensible decisions, difficulties sometimes arise in the daily implementation of QA policies and procedures. Most EPA employees are passionate about the Agency's mission in general, but some aspects of their jobs that are not perceived to be *directly* related to that mission sometimes receive less attention and respect than those that are. Some parts of the EPA QA community frequently struggle with the perceptions and preconceived notions of some of some of their non-QA coworkers that must implement the QA requirements. Due to their belief by QA professionals that the EPA Quality System[2] adds tremendous value and reliability to the Agency's mission, their professional relationships with those coworkers can become strained at times. Their non-QA coworkers may feel that the QA requirements are externally imposed or confusing, and hence do not feel a sense of ownership with regard to QA policies. The best approach to address resistance or confusion is through increased and sustained communications and education[3]. Having used these techniques to successfully increase our level of support from EPA management, perhaps it is time to shift our attention to other stakeholder groups as well.

Case Study

To promote a discussion of how the QA community can increase employee understanding of EPA QA policies and procedures, and hopefully thereby improve execution of those policies and procedures, a case study will be presented that illustrates previous successful efforts of QA outreach and proposes areas for further improvement. The principles reflected in this case study can be applied to project management, program planning, and implementation of procedural changes, large or small. The hope is for QA professionals to become more sagacious and effective leaders in their future efforts. EPA is an Agency in transition as it endures the inevitable attrition of many of its long-term employees and the constant influx of new ones, and there is a distinct need for continuous communication and outreach to newer employees about EPA's QA requirements.

In years past, it was difficult to ensure that appropriate QA requirements would be included in all contracts and grants, even though EPA Order 5360.1[4] states that all environmental programs performed by EPA or directly for EPA through EPA-funded extramural agreements shall be supported by individual quality systems that comply fully with the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*.[5] The disparity was due to a lack of understanding between the EPA QA Community and EPA's Office of Acquisition Management (OAM) about their respective policies and procedures. Each had a complex system of processes that rarely required interaction between the two organizations, but many hurdles were overcome once a meaningful dialog was initiated.

The Federal Acquisitions Regulation (FAR) System, described in 48 CFR[6], mandates the acquisition regulation applicable to all executive agencies of the Federal Government. The EPA

Contracts Management Manual (CMM)[7] EPA Directive 1900, codifies the policies and procedures specific to EPA which implement and supplement the FAR. Over five years ago, OAM initiated revisions to the CMM, Directive 1900. To ensure compliance with EPA Order 5360.1, they planned to devote a chapter to QA requirements for contracts. They appropriately contacted EPA's Quality Staff and asked them to form and lead the CMM Workgroup comprised mainly of QA experts that could advise them in developing appropriate QA policies and procedures. This task included developing a newly required Quality Assurance Review Form (QARF) for the purpose of ensuring appropriate QA requirements were included in EPA contracts, writing Chapter 46 of the CMM which would describe the new form and policies, and developing a guidance website that would be available on the EPA's intranet. The resultant QARF for contracts was a mechanism to allow CORs and QA Managers (QAMs) to collaboratively choose the project-specific QA requirements from a list of possible options in a format that the Contracting Officers (COs) could easily understand and communicate to contractors though the clauses of the contract.

Even if not true in reality, at the time, OAM and the QA community each *perceived* the other to be rife with confusing requirements and burdened with a high level of administrative bureaucracy, which may have dissuaded some from participating in this joint effort. However, this directive would have a very *direct* impact on the usual work routine of the EPA's QA professionals, and serving on this workgroup was a significant opportunity to have a voice in how QA could adequately be covered in contracts. In part due to the fact that Directives typically remain in force without revision for long periods of time, some QA professionals could see how big the stakes were and saw the value in securing the vital interest of proper application of QA to ensure that EPA products are accurate, defensible, and respected. However, even though the call for volunteers went out to all programs, regions, and offices, many did not respond to the call.

The volunteers for the workgroup were highly motivated and focused on creating documentation and procedures that would provide a win-win situation for the QA community and OAM. They could be considered to be not just "participants" in the EPA Quality System, routinely going about their duties, but actual "champions" of quality who work to advance the field of quality overall, not just the individual or his organization[8]. A champion of quality provides vision, leadership, and support for a particular effort or initiative; provides resources to help accomplish the initiative; and can remove obstacles that impede progress[9]. The volunteers on the workgroup advanced quality concepts by being willing to communicate with another organization outside the scope of their regular duties and made commendable efforts to satisfy the needs of stakeholder groups.

Accomplishing the CMM Workgroup's Mission

The scope of the CMM workgroup's mission was daunting. They had been tasked with developing one policy and one QARF that would fit the needs of the *entire* Agency. That effectively eviscerated two of the first principles of organizational change. The team would *not* be able to keep this change "simple." Moreover, being just one of many changes to the contracts manual slogging through the directives clearance process, it would not be able to "act quickly."

However, during the course of five years, it successfully accomplished the tasks with which it was charged by OAM. The team:

- Asked for volunteers from across the Agency,
- Deliberated its decisions thoroughly,
- Included a high-level member from OAM with expertise in contracting,
- Solicited input from the QA community often,
- Followed the established procedures for directives clearance,
- Asked two CORs in each member's organization to review the draft documents in detail,
- Developed the QARF,
- Authored a chapter of instruction for the CMM, and
- Created a guidance website for using the QARF.

On a local level some individual team members made the implementation go more smoothly by:

- Discussing the workgroup's efforts early on with the QA community in their respective Offices, including the Directors of Quality Assurance (DQAs),
- Asking for input on tailoring the QARF to fit local needs,
- Brainstorming about all project situations and contingencies,
- Making presentations at annual EPA national QA meetings,
- Making presentations at annual meetings for their Offices, and
- Presenting training to their Office QA community and Division CORs.

Implementation of the CMM

The overall cooperative effort between the QA community and OAM was a huge success in terms of developing the processes to ensure adequate QA requirements were included in all contracts with minimal additional effort imposed on the various stakeholder groups within EPA. This groundbreaking coordination of organizational needs was indicative of the success the QA community had with securing management support, followed by OAM support. However, because the QA effort was tied to the much larger, total CMM revision effort, the implementation stages presented some unexpected difficulties. Months after the workgroup had completed its portion of the effort, OAM issued the new CMM without providing any Agency-wide notice or training, so many people were unaware of the changes until the news trickled down over time.

This presented an unexpected hurdle to efficient implementation of the new QA requirements. The workgroup member from OAM had informed the workgroup earlier that OAM planned to train all of their personnel when the CMM was issued, and the team *assumed* that because the CMM is "owned" and enforced by OAM, the local Contracts Service Centers would provide their CORs with training on their new requirements. The workgroup had simply served as a group of consultants – and *only* regarding the QA issues, which was a very small part of the CMM document. Upon asking the workgroup's OAM member about its planned training, the workgroup was told that the training would be delayed and that the QA community would be responsible for training the CORs. Since they wanted the new requirements to be implemented as intended, the workgroup members would be required to train the rest of the QA community.

Implementation of the QARF

Three of the workgroup members were from my Office, and I had expected that we would have an easier time training the rest of the Office's QA personnel than would other workgroup members in their less involved organizations. However, the process was not as easy as I had expected. Despite our having spoken about the efforts of the workgroup and solicited input numerous times, several of the QA professionals were surprised to learn of *new* requirements, and some were unsatisfied with what the workgroup had produced. It took more effort than expected to train them sufficiently to enable them to train their CORs on the QARF.

As the various organizations in my Office began implementing the QARF, it became apparent to me that this was occurring in a very inconsistent manner. Somehow, not everyone had heard the same set of instructions that we *thought* we had given out. In general, misunderstandings about the use of the form increased as training filtered down to the CORs. The biggest problem was that none of the CORs understood the reason for the changes, and therefore were very resistant to them. Somehow, our instructions had not come across as clearly as we had expected. Many CORs complained that they couldn't make heads or tails of the form, and unfortunately, their QAMs were confused as well. People at all levels were entirely unwilling to even take a look at the guidance website and even unwilling to call and ask the workgroup members questions. In the initial stages of implementation, it was difficult to ensure that CORs were adequately trained to complete the form correctly, but after they had time to work with the form in the course of their duties, they were better equipped to seek out the specific information that they needed.

Attitude for Quality Improvement

In a large organization it is easy to look at something that didn't go quite according to plan and say that it's "not my problem". However, I knew that this certainly wouldn't be the last time in my career that I worked on a project or was a member of a workgroup where things might go wrong, so I genuinely searched for ways we could have improved. In a recent Project Management Training at EPA headquarters, during a segment on reaching all of a project's stakeholders during the planning stages, I asked the class of twenty bright and enthusiastic people what they thought could have been done to make the implementation go more smoothly. Having only a brief description of the project, they suggested actions like:

- Give people an opportunity to participate in the workgroup,
- Make sure you have all areas of stakeholders covered,
- Ask for input from each group of stakeholders,
- Have written guidance, and
- Provide training.

When I responded that we *had* done each of those things, including asking for input from all levels on numerous occasions throughout development of the documentation, many shook their heads and let out a sigh of exasperation. Phrases like "typical", "government inertia", and "too many other fires" drifted up from some. Several nearby me nodded slowly and said, "I know

just what you mean." The most outspoken person in the class threw up his hands and said loudly, "Well, that's just *too bad*! They missed their chance to provide input, and now they're just going to have to live with it." While I might have agreed with them on some level, I knew that was not the attitude that would provide me with any tools to improve the situation in the future. To be callous and indifferent to the concerns of any of our stakeholders would damage the reputation of the QA community and perpetuate miscommunication about the role of quality assurance in the Agency.

Planning, Leadership, and Communication

It can be said that "implementation as an area of study was born of a need to understand why policy changes imposed from the top often did not find their way to the bottom of large organizations, or if they did, why they resided there in substantially altered form[10]." Let's take a closer look at the process the CMM workgroup used and see what could have been improved. Keep in mind that this examination could be applied to many of the types of work we do as QA professionals, not just this specific example. I believe that an expanded, more personal level of communication with all of the stakeholders was the largest improvement that could have been made. Yes, there were scores of mass email communications sent out soliciting input on the workgroup's activities, but did they *reach* the most critical people, and did they get the right message across?

Perhaps the largest impediment to adequate communication about the QA workgroup's mission was the lack of an enthusiastic leader/champion of the overall effort in OAM. Information and education were key to the success of this effort, and increased communication from a champion might have successfully combated the confusion and inaction exhibited from management, the general QA community, and the community of CORs. The CMM workgroup members may not have had control over the direction of leadership and planning in OAM, but we can use this example as a lesson to us when managing our own projects, both organizationally and individually. Changes, like causes, need an enthusiastic leader, a champion to drive them. Unless people see a legitimate need for the change, they will resist it. Potential methods of overcoming resistance to change include[11]:

- Education and communication.
- Participation and involvement.
- Facilitation and support.
- Negotiation and agreement.

The leader/champion must instigate the change by being visionary, persuasive, and consistent. This vision must be translated into a realistic plan and then implemented. This role cannot be delegated down to the next level unless the leader successfully converts the delegate into a champion of the cause in his own right. OAM should have planned their operation past the point of delegating pieces of it to various unempowered workgroups. As stated previously, there were many organizations that did not respond to the call for volunteers for the workgroup. To ensure success, OAM should have ensured that all large organizations had members on the workgroup committed to championing the cause, and they should have ensured that the scope of the workgroup's mission was clear and definitive within the scope of the entire operation. It is likely

that the call for volunteers was simply not regarded as important enough by various organizations.

Once the workgroup volunteers had convened, they began working on the "concrete" projects that they had been tasked with: development of the QARF and associated documentation and guidance. Although they had the best intentions, it appears in retrospect that they made several unspoken assumptions based on the information that they had from OAM:

- OAM was responsible for the overall success of the CMM policy revisions.
- OAM would be responsible for implementation of the revised procedures.
- Since OAM had charged the workgroup with its mission, our priority was to satisfy OAM's needs.
- If management signed off on it, they would ensure compliance within their organizations.
- It would be obvious to most QAMs and CORs why the changes in the QA requirements for contracts were necessary to further the EPA's mission.

Having made those assumptions, the workgroup proceeded to work toward accomplishing their charge from OAM. In addition to all of the typically prudent actions undertaken by the workgroup members, there were several missed opportunities for improvement that could have greatly affected the outcome. Even if the CMM workgroup was not primarily responsible for leading some of these actions listed below, they should have ensured that someone in OAM was handling them. In retrospect, the workgroup's tasks should have included:

- Carefully identifying all "customers" and their unique needs,
- Brainstorming about future obstacles to the process,
- Considering the separateness of the different stakeholder groups,
- Coordinating with OAM, management, and the EPA Quality Staff to present information in a consistent manner with the proper authority behind it,
- Planning for implementation by end users,
- Looking for ways to overcome expected resistance to change,
- Realizing that some degree of "marketing" would be necessary, and
- Using frequent *personal* communication efforts within their organizations.

Identifying Our Stakeholders/Customers

The concept of QA professionals having "customers" may be a somewhat novel concept, however, everyone is familiar with the concept of stakeholders. Different stakeholders have different priorities, and due to the high level of operational isolation among various groups within the government, their priorities may be unknown to each other. In this case, what made the QARF process simpler for OAM made the process very convoluted for CORs. In an attempt to condense every possible QA option for contracts into a fairly short and recognizable section for the personnel working in OAM, the myriad of options for the CORs to choose from was obscured from them, and even explaining to them how to access the true versatility of the QARF became difficult. There are significantly more CORs throughout EPA than there are COs and contracts specialists in OAM, yet the CORs lack any central organization to look out for their interests. However, the QA community must interact with CORs as "customers" of our services

on a daily basis, while we interact with OAM personnel rarely. Perhaps if the workgroup had done a more thorough analysis of their stakeholders/customers needs during the planning stages of their project, the end result might have been closer to a win-win situation for *all* parties.

Planning for Obstacles to Change

Generally, it is human nature to resist change. People will not accept change unless they understand it is required to accomplish an important overall goal. In this case, the workgroup was unable to (1) communicate to its customers, the CORs, what the goal *was*, and (2) to convince them that it was worthwhile. Early consideration of several factors could have increased the likelihood that the workgroup could address the concerns of end users of the QARF during the implementation stage. These include:

- Universal dislike of externally imposed policies,
- Organizational culture and values,
- Current policy context,
- Lack of support from OAM and Management, and
- Lack of oversight and/or consequences for noncompliance.

Individuals can have a high amount of disdain for requirements that are the result of a top-down push from outside of their organization. There may be heavy resistance to any externally imposed requirement for which individuals can feel no "ownership", especially when they feel that it is at odds with the culture or values of their local organization. Many Government employees feel that they already have a very heavy bureaucratic burden and complain about any additional paperwork that they may have to learn to manage. They want to focus on the meat of EPA's mission, stating, "just let me do science". Because most changes come about so slowly, those affected often do not evaluate the changes until they are actually implemented because there are always bigger fires to put out.

In addition we should view changes in the context of other issues facing EPA employees today. Budget and staff cuts have piled additional job duties on most employees already, paperwork continues to increase from all directions, some employees already regard QA with confusion and defensiveness, and it is always hard to get everyone together for a long enough time to provide adequate training on new requirements.

It would have been helpful a contingency plan ready in case either OAM or management failed to follow-through with implementation training and oversight, and that would have required that the workgroup pinpoint a mechanism for identifying if or when the ball gets dropped and a contingency plan should be implemented. Another facet to investigate would have been identifying the effects of a potential lack of consistent oversight and the fact that there are few consequences for noncompliance. If feasible, a pilot study in a target organization may be appropriate[12]. Also, because there are many reasons why people may not come forward with questions or feedback, monitoring procedures can be planned in advance such that people are asked about problems, for example, through regular implementation surveys[13].

Communication and Marketing for QA

Effective communication involves basic skills in speaking, listening, questioning, and sharing feedback. The QA community needs to convey to other organizations and customers that we value hearing from others and their hearing from us. Widely distributed e-mail is too often a one-way form of communication. It is easy to ignore, and even easy to forget about even if you do read it. It is a very non-personal and ironically ineffective form of communication because the interchange typically only involves one of the basic skills cited above: in effect, "speaking". Personal communication, the kind that can only be accomplished one-on-one or in small groups, is a much more effective tool for educating, persuading, and energizing people. We as a QA community have a lot of history and prejudice to overcome regarding our job duties and the way we interact with other organizations. We need to change our customers' values and opinions and the way that they enact them in the course of their duties. Until they agree that we serve a legitimate need within the Agency, we will never become an accepted priority in their work.

It is likely that few of us in the QA community have ever thought that our job duties include "marketing" our services and ourselves. "Marketing" is the process of planning and executing the conception, pricing (value), promotion, and distribution of goods, services, and ideas to create exchanges that satisfy individual and organizational objectives[14]. It includes the activities of listening to customer needs, assessing the competitive landscape and then designing and creating products and services accompanied by messages that shape audience perceptions. As a concept, it is gaining increased attention at EPA, as various organizations realize that they cannot continue to operate in a vacuum. Competition between programs for resources and priority will only escalate. The EPA QA community should start considering how we might utilize our planning processes and resources to further shape the perceptions and actions of our various stakeholders/customers.

Conclusion

The EPA QA community has been very successful at increasing their visibility and support base across many organizational lines but should not grow complacent with their success. With previous experiences under our belts, we should be ready to use some of our tools in new ways. The concept of "marketing" may prove useful to us in our efforts to continue educating EPA employees in quality principles and their usefulness to the Agency. QA professionals should continue to improve their communication and leadership skills that will enable them to become "champions of quality" at EPA. Development of effective training programs is critical to the continued success of our programs. During planning processes, we should seek to identify and include all groups of stakeholders/customers in our considerations, and we should solicit their feedback whenever possible. Planning ahead for potential obstacles to change implementation with contingency plans should be elevated to a higher priority. We should continue to expand our connections to other organizations, and whenever necessary we should take the lead in ensuring that correct and consistent messages are delivered to our customers throughout the Agency.

References

[1] Ponder, W. 2002. The Importance of a Successful Quality Assurance (QA) Program from a Research Manager's Perspective. *Quality Assurance: Good Practice, Regulation, and Law* 9: 173-178.

[2] U.S. Environmental Protection Agency. (2000a). *EPA Quality Manual for Environmental Programs* (EPA 5360 A1). Washington, DC.

[3] MAP for Non-profits, *Free Management Library, Basic Context for Organizational Change*, http://www.managementhelp.org/mgmnt/orgchnge.htm, accessed March 2005.

[4] U.S. Environmental Protection Agency. (2000b). *Policy and Program Requirements for the Mandatory Agency-wide Quality System* (EPA Order 5360.1 A2). Washington, DC.

[5] ANSI/ASQC E4:1994, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, American National Standard, American Society for Quality, Milwaukee, WI (January 1995).

[6] 48 CFR, Code of Federal Regulations, *Federal Acquisition Regulations*.

[7] EPA Intranet, Directive 1900, *Contracts Management Manual*, April, 2004, http://epawww.epa.gov/oamintra/policy/cmm.pdf, accessed March 2005.

[8] American Society for Quality, *Champions of Quality*, http://www.asq.org/news/interest/champion.html, accessed March 2005.

[9] American Society for Quality, *How do you define a "champion of quality?"*, http://www.asq.org/news/interest/definechampion.html, accessed March 2005.

[10] RAND Corporation, *Sexual Orientation and U.S. Military Personnel Policy: Options and Assessment*, Chapter 12, *Implementing Policy Change in Large Organizations*, p. 369, http://www.rand.org/publications/MR/MR323/mr323.ch12.pdf, accessed March 2005.

[11] Oakland, J.S. (1993). *Total Quality Management*, (*Second Edition*). New Jersey: Nichols Publishing.

[12] U.S. Environmental Protection Agency. (2002). *Guidance for Developing Quality Systems for Environmental Programs* (*QA/G-1*) (EPA/240/R-02/008). Washington, DC.

[13] Gottlieb, Nell, Chris Lovato, Riki Weinstein, Lawrence Green, and Michael Eriksen, *The Implementation of a Restrictive Worksite Smoking Policy in a Large Decentralized Organization*, Health Education Quarterly, Vol. 19, No. 1, 1992, pp. 77-100.

[14] *Marketing Notes: Chapter 1*, http://www.andrew.cmu.edu/user/dnama/printing/Microsoft%20Word%20-%20Ch1%20Marketing%20Notes.pdf, accessed March 2005.

Determining the Competence of Auditors

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Introduction:

The successful implementation of any assessment or audit program depends on the competence of the auditors selected and their subsequent performance in conducting the audit program. Audit programs are intended to add value to an organization's quality or environmental management system implementation. To accomplish this goal, the audit programs must ensure that the auditors are competent to conduct the audits.

According to ISO 19011:2002, *Guidelines for Quality and/or Environmental Management Systems Auditing*, auditor competence is based on the demonstration of appropriate personal attributes and the ability of the individual to apply adequate knowledge and skills to specific audit programs. The needed knowledge and skills would be acquired through education, work experience, auditor training, and audit experience, and would encompass subject matter knowledge of audit processes and well as the management or technical systems to be audited and the criteria or standards upon which the management systems are based.

The most effective approach to determining the needed auditor competence is based on the scope of the audit program. In this way, the needed knowledge and skills may be tailored to fit the specific objectives of the audit program. Accordingly, this paper outlines the general considerations for determining auditor competence that may be applied to internal or external audit programs. There are important differences between internal and external audit programs which affect the depth of knowledge and extent of skills needed for such audits and their application. Each of the key elements for competence will be described as will a general process for selecting and evaluating auditors to ensure the continued effectiveness of the audit programs and the confidence of the customer in those programs.

The Concept of Competence

The success of any audit program will depend on the confidence and reliance of the participants in the audit process implementation and the competence of those conducting the audit. Auditors are made, not born. Auditors must demonstrate necessary personal attributes and the ability to apply knowledge and skills gained through appropriate education, work experience, auditor training, and audit experience. Moreover, competence is static. It is dynamic and must be maintained through an effective continual professional development program in order to ensure that audit program needs can be met.

Auditor competence encompasses the following elements for in order to achieve competent auditors:

- personal attributes,
- general knowledge and skills related to auditing principles and practices,
- general knowledge and skills for audit team leaders,
- specific knowledge and skills that may apply to quality or environmental management systems auditing, and
- considerations for levels of education, work experience, auditor training, and audit experience.

Elements of Competence:

Personal Attributes:

Auditors should possess the necessary personal attributes to enable them to implement the prescribed audit plan successfully. In general, an auditor should be:

- ethical (i.e., fair, truthful, sincere, honest and discreet);
- open minded (i.e., willing to consider alternative ideas or points of view);
- diplomatic (i.e., tactful in dealing with people);
- observant (i.e., actively aware of the surroundings and activities);
- perceptive (i.e., instinctively able to understand situations);
- versatile (i.e., able to adjust readily to changing situations and conditions);
- tenacious (i.e., persistent and focused on achieving the objectives);
- decisive (i.e., able to reach timely conclusions in a logical manner); and
- self-reliant (i.e., able to act independently while interacting with others).

In addition, it is also important that an auditor demonstrate the willingness to be an auditor and to be able to work as part of a team.

General Knowledge and Skills Related to Auditing Principles and Practices:

Clearly, an auditor must demonstrate knowledge and skills pertaining to general auditing practices, including basic auditing principles. Auditors must be able to apply this knowledge consistently and in a systematic manner to ensure the success of the audit.

An auditor should be able to:

- to apply audit principles, procedures and techniques,
- to plan and organize the work effectively,
- to conduct the audit within the agreed time schedule,
- to prioritize and focus on matters of significance,
- to collect information through effective interviewing, listening, observing, and by reviewing documents, records, and data,

- to understand the appropriateness and consequences of using sampling techniques for auditing,
- to verify the accuracy of collected information,
- to confirm the sufficiency and appropriateness of audit evidence to support audit findings and conclusions,
- to assess those factors that can affect the reliability of the audit findings and conclusions,
- to use work documents to record audit activities,
- to prepare audit reports,
- to maintain the confidentiality and security of information, and
- to communicate effectively.

These skills may be acquired during the training of internal auditors, which should focus on not only the skills involved, but also the particular procedures, forms and requirements of the internal audit program. The application of these auditing skills need only be covered in the context of the internal audit program. In some internal audit programs, the role of the auditor is limited with many of the tasks listed above actually carried out by the audit program manager acting as a leader of the audit team. Therefore, the expectations of the auditor's role should determine the skills and knowledge needed.

Auditors should understand the applicable management system and reference documents. This is necessary to enable the auditor to comprehend the scope of the audit and apply audit criteria. Knowledge and skills in this area should cover:

- the application of management systems to different organizations,
- interaction between the components of the management system,
- quality or environmental management system standards, and applicable procedures or other management system documents used as audit criteria,
- recognition of differences between and priority of the reference documents,
- application of the reference documents to different audit situations, and
- information systems and technology for, authorization, security, distribution and control of documents, data, and records.

Auditors should know how the particular management system, in which they work, functions. The skills and knowledge in this area should focus on the particular management system documents such as the management system manual, procedures, work instructions and other specific management system requirements. There does not necessarily need to be a focus on international management system standards or the application of standards in external organizations. Any external reference documents need only be covered as they apply to the management system.

An auditor should understand relevant organizational situations in order to enable the auditor to comprehend the organization's operational context. Knowledge and skills in this area should cover:

- organizational size, structure, functions and relationships,
- general business processes and related terminology, and
- any cultural aspects of the organization audited.

An auditor should understand or at least have a working knowledge of applicable laws, regulations and other requirements relevant to the discipline. This is needed to enable the auditor to work within, and be aware of, the requirements that apply to the organization being audited. Knowledge and skills in this area should cover:

- local, regional and national codes, laws, and regulations,
- contracts and agreements,
- international treaties and conventions, and
- other requirements to which the organization subscribes.

Internal auditors should be able to audit within the organization’s culture; therefore, new employees should be given the time necessary to adapt to the organization before being assigned audit responsibilities. Skills and knowledge of laws, regulations and other requirements should focus on those actually applicable to the organization or the products and processes. In some organizations there is limited knowledge of the laws and regulations and their applicability, which may suggest consideration of external assistance.

General Knowledge and Skills for Audit Team Leaders:

Audit team leaders should have appropriate additional knowledge and skills in audit leadership to facilitate the efficient and effective conduct of the audit. Such skills will place emphasis on strong personal attributes relating to communications, demeanor, and emotional stability. An audit team leader should be able:

- to plan the audit and make effective use of resources during the audit,
- to represent the audit team in communications with the auditee,
- to organize and direct audit team members,
- to provide direction and guidance to auditors-in-training,
- to lead the audit team to reach audit conclusions,
- to prevent and resolve conflicts, and
- to prepare and complete acceptable and timely audit reports.

For those audits in which there is only one auditor, that auditor should have the knowledge and skills applicable to the functions assigned to that auditor as the audit team leader. Leadership skills and knowledge for an audit team leader may be demonstrated by leadership/supervisory positions held in the organization. Leadership skills may also be demonstrated in activities outside of the organization.

Specific Knowledge and Skills for QMS and EMS Auditing:

Quality management system auditors should have knowledge and skills pertaining to quality methods and techniques and to the related processes and products. The auditor should understand quality-related methods and techniques in order to enable the auditor to examine quality management systems and to generate appropriate audit findings and conclusions. Knowledge and skills in this area should cover:

- quality terminology,
- quality management principles and their application, and
- quality management tools and their application (for example statistical process control, failure mode and effect analysis, etc.).

The auditor should also understand related processes and products, including services in order to enable the auditor to comprehend the technological context in which the audit is being conducted. Knowledge and skills in this area should cover:

- sector-specific terminology,
- technical characteristics of processes and products, including services, and
- sector-specific processes and practices.

The needed quality related knowledge and skills of the auditors may vary from organization to organization and from audit to audit within an organization.

Environmental management system auditors should have knowledge and skills pertaining to environmental management methods and techniques, applicable environmental science and technology, and the technical and environmental aspects of the operations being audited. The auditor should understand environmental management methods and techniques in order to enable the auditor to examine environmental management systems and to generate appropriate audit findings and conclusions. Knowledge and skills in this area should cover:

- environmental terminology,
- environmental management principles and their application, and
- environmental management tools (such as environmental aspect/impact evaluation, life cycle assessment, environmental performance evaluation, etc.).

The auditor should understand environmental science and technology in order to enable the auditor to comprehend the fundamental relationships between human activities and the environment. Knowledge and skills in this area should cover:

- impact of human activities on the environment,
- interaction of ecosystems,
- environmental media (e.g. air, water, land),
- management of natural resources (e.g. fossil fuels, water, flora and fauna), and
- general methods of environmental protection.

The auditor should also understand appropriate technical and environmental aspects of operations in order to enable the auditor to comprehend the interaction of the auditee's activities, products, services and operations with the environment. Knowledge and skills in this area should cover:

- sector-specific terminology,
- environmental aspects and impacts,
- methods for evaluating the significance of environmental aspects,
- critical characteristics of operational processes, products and services,
- monitoring and measurement techniques, and
- technologies for the prevention of pollution.

For internal audit programs, the environmental related knowledge and skills may only relate to the environmental aspects, methods, and techniques applicable to the organization. For example, the specific aspects and impacts, monitoring and measurement techniques, and prevention of pollution activities relevant within the organization should be considered. Specialized environmental knowledge or certifications could be used as indicators of competence.

Considerations for Levels of Education, Work Experience, Auditor Training, and Audit Experience:

Auditors should have the necessary education, work experience, auditor training and audit experience in order to plan and implement the audit program. In general, auditors should have:

- completed an education sufficient to acquire the knowledge and skills needed.

- work experience that contributes to the development of the knowledge and skills needed for the audit program. This work experience should be in a technical, managerial or professional position involving the exercise of judgment, problem solving and communication with other managerial or professional personnel, peers, customers and/or interested parties. Part of the work experience should be in a position where the activities undertaken contribute to the development of knowledge and skills in:

  - the quality management field for quality management system auditors, and
  - the environmental management field for environmental management system auditors.

- completed auditor training that contributes to the development of the knowledge and skills needed. This training may be provided by the person's own organization or by an external organization.

- audit experience in the planning and conducting audit activities. This experience should have been gained under the direction and guidance of an

auditor who is competent as audit team leader in the same discipline. The extent of direction and guidance needed during an audit should be at the discretion of those assigned responsibility for managing the audit program and the audit team leader. The provision of direction and guidance does not imply constant supervision and does not require someone assigned solely to the task.

The establishment of minimum levels for education, training, and experience will not necessarily ensure that the needed auditor competencies can be achieved. A more effective approach is to identify the specific competencies needed for a specific audit program and to evaluate each auditor relative to those required competencies. The competence-based approach for individual audit programs allows organizations to develop auditor competencies tailored to the specific needs of the audit program and can provide more flexibility in evaluating auditors. For example, internal audit programs may have the opportunity to directly observe auditors in both audit and other job related activities. This can provide the opportunity to evaluate personal attributes, skills, and knowledge in auditing activities, training activities, and work activities that may translate into the needed auditor competencies.

For internal audit programs, the approach of defining minimum levels of education, training and experience is generally not appropriate. If persons have demonstrated the appropriate personal attributes, and relevant skills and knowledge in the performance of their jobs; then this demonstration can be accepted. For the auditing skills and knowledge, which are acquired during the training and auditing activities, demonstration of the use of the skills is preferred. Practical application of these auditing skills should be demonstrated through performance of audits. The evaluation of personal attributes, skills and knowledge is critical to assure competence.

An audit team leader should have acquired additional audit experience to develop the knowledge and skills described earlier. This additional experience should have been gained under the direction and guidance of another auditor who is competent as an audit team leader. The need for audit team leaders depends upon the nature of the organization and its audit programs. In some cases, audits are accomplished by a single auditor rather than a multi-person team. The audit experience under the guidance of an audit team leader may not be necessary in many internal and some external programs.

Mentoring and coaching by an experienced audit team leader can provide an effective means of developing the additional knowledge and skills needed. The organization should consider and identify the specific knowledge, skills, and personal attributes needed by the mentor or coach. For internal audit programs, the demonstration of leadership skills can be accomplished in roles other than that of audit team leader. For example, experience in supervisory positions, leadership of other types of teams or leadership in civic organizations could adequately demonstrate these skills.

Quality management system or environmental management system auditors who wish to become auditors in the second discipline should have the training and work experience needed to acquire the knowledge and skills for the second discipline, and should have conducted audits covering the management system in the second discipline under the direction and guidance of an auditor

who is competent as an audit team leader in the second discipline.

An audit team leader in one discipline should meet the above recommendations to become an audit team leader in the second discipline.

The skills and knowledge necessary for auditors who audit in both disciplines will depend upon the needs of the audit program and the complexity of the second discipline in the organization. There will be a need for some demonstration of skills in the second discipline, but simply setting minimum levels of education, training and experience is generally not appropriate for internal and most external audit programs.

Attaining the skills and knowledge for competence in a second discipline may be difficult for some auditors to accomplish. While auditing principles are generally the same for both disciplines, the knowledge and skills unique to quality management systems and to environmental management systems can be difficult for an auditor to master. For example, a QMS auditor may find that the terminology and background information needed for EMS audits requires considerable effort to master sufficiently to be able to perform audits. Similarly, an EMS auditor may find that some aspects of quality control and quality assurance practices are a challenge to master.

Organizations should establish the levels of the education, work experience, auditor training and audit experience an auditor needs to gain the knowledge and skills appropriate to audit program by applying Steps 1 and 2 of the Evaluation Process described later. As discussed previously, a more effective approach is to identify the specific competencies needed for a specific audit program and to evaluate each auditor relative to those required competencies. The competence-based approach for individual audit programs allows organizations to develop auditor competencies tailored to the specific needs of the audit program and can provide more flexibility in evaluating auditors.

For audits performed by an auditor coming from a different discipline, it is very important that the required knowledge and skills in the second discipline have been accomplished and demonstrated sufficiently. Internal auditors may be evaluated in their job functions and auditing activities. This evaluation should be based on the knowledge and experience needed for the specific audit program. In taking this approach, it may be necessary to evaluate the application of the skills and knowledge in functions other than auditing, such as leadership and communications.

Selection of Auditors:

The selection process for auditors must first consider the type, scope, and objectives of the audit program. The competence criteria will be based on the audit program so that an appropriate auditor team can be selected that will enable the audit program objectives to be met. For example, the competence criteria for auditors in an external, third-party audit program will generally be different from the criteria for auditors in an internal audit program.

In general, the following steps constitute the auditor selection process for a particular audit or

audit program:

- Identification of potential auditors and their initial evaluation against the applicable criteria for the audit or audit program.
- Provide any special training in auditing and provide for necessary additional audit experience through mentored audits.
- Evaluate potential audit team leaders for the audit or audit program.
- Select the audit team leader and auditors for the specific audit that provides the best match of competence with the objectives of the audit.
- Following an audit, the audit team is evaluated to assess there performance and to identify areas wherein improvement may be needed.

Evaluation of Auditors:

The evaluation of auditors and audit team leaders should be planned, implemented and recorded in accordance with audit program procedures to provide an outcome that is objective, consistent, fair and reliable. The evaluation process should identify training and other skill enhancement needs. The evaluation of auditors occurs at the following different stages:

- the initial evaluation of persons who wish to become auditors,
- the evaluation of the auditors as part of the audit team selection process, and
- the continual evaluation of auditor performance to identify needs for maintenance and improvement of knowledge and skills.

For auditors moving into a second discipline, it is very important that the initial evaluation give special attention to confirming that the auditor has demonstrated sufficient knowledge, skills, and experience in the second discipline. Subsequent evaluations should also confirm that the necessary competence for the second discipline is maintained.
The evaluation process involves four main steps.

- **Step 1: Identify the personal attributes, and the types and extent of knowledge and skills to meet the needs of the audit program.**

  In deciding the appropriate types and extent of knowledge and skills the following should be considered:

  - the size, nature and complexity of the organization to be audited,
  - the objectives and extent of the audit program,
  - certification/registration and accreditation requirements,
  - the role of the audit process in the management of the organization to be audited,
  - the level of confidence required in the audit program; and
  - the complexity of the management system to be audited.

- **Step 2: Set the evaluation criteria.**

  The criteria may be quantitative (such as the years of work experience and education, number of audits conducted, hours of audit training) or qualitative (such as having demonstrated personal attributes, knowledge or the performance of the skills, in training or in the workplace). The evaluation process as described here should be used by internal audit programs. An internal audit program has an advantage in that some of the competencies of the auditors can be evaluated based on performance in jobs other than auditing. In addition, the evaluation of auditing skills by direct observation may be logistically easier in internal audit programs.

- **Step 3: Select the appropriate evaluation method.**

  Evaluation should be undertaken by a person or a panel using one or more of the methods selected from those given below. In general, the methods outlined represent a range of options and may not apply in all situations; the various methods outlined can differ in their reliability. Typically, a combination of methods should be used to ensure an outcome that is objective, consistent, fair and reliable. The methods include:

  - records review,
  - positive and negative feedback,
  - interviews,
  - observation,
  - testing, and
  - post audit review.

- **Step 4: Conduct the evaluation.**

  In this step the information collected about the person is compared against the criteria set in Step 2. Where a person does not meet the criteria, additional training, work and/or audit experience are required, following which there should be a re-evaluation. Internal audit programs can use the observation of audit activities to evaluate auditors as they utilize the needed audit skills in actual audit situations and in other non-audit situations that require the same skills. Internal feedback can be obtained from a variety of individuals who interact with the potential auditor from different perspectives. The emphasis should be on the direct observation of skills rather than the collection of records.

Continual Professional Development:

Continual professional development is concerned with the maintenance and improvement of knowledge, skills and personal attributes. This can be achieved through means such as additional work experience, training, private study, coaching, attendance at meetings, seminars and conferences or other relevant activities. Auditors should demonstrate their continual

professional development. The continual professional development activities should take into account changes in the needs of the individual and the organization, the practice of auditing, standards and other requirements.

Continual professional development for auditors could encompass staying up-to-date on changes to the auditor's management system, management system standards or criteria, the audit program, and any competence needs identified by the audit program manager. Other methods for obtaining continual professional development include refresher training, participation in local environmental or quality organization meetings, courses at community colleges and other similar activities.

Auditors should maintain and demonstrate their auditing ability through regular participation in audits of quality and/or environmental management systems. All auditors should have a minimum audit participation level; however, this level should be defined by the audit program manager within the context of the audit program.

Summary and Conclusions:

The success of any audit program depends largely on the competence of the auditors. Again, auditors are made, not born. They must demonstrate appropriate knowledge, skills, education, experience, and personal attributes to meet the needs of the audit program. Moreover, auditors must be evaluated in a systematic manner and must ensure their on-going competence through appropriate continual professional development.

References:

1. ISO 19011:2002, *Guidelines for Quality and/or Environmental Management Systems Auditing*, International Standard, Geneva (October 2002).

1. ANSI/ISO/ASQ QE 19011S-2004, *Guidelines for Quality and/or Environmental Management Systems Auditing - U.S. Version with Supplemental Guidance Added*, American National Standard, ASQ, Milwaukee (August 2004).

Title: A Bayesian approach to measurement detection limits

Author: Bradley Venner

Abstract:

A Bayesian approach to detection limits has some advantages over traditional frameworks. First, it is relatively straightforward to include calibration error, which has been a source of some confusion in the literature. Second, the approach is easily generalized beyond the constant additive model used by Currie to multiple responses and non-constant error models. Third, utilities can be used to model the consequences of incorrect decisions, which generalize the Neyman-Pearson hypothesis testing framework that dominates the existing approaches; this approach can be extended to multiple decision-makers in a straightforward manner. This paper develops the approach in general, analyzes in detail the constant error model, and identifies problems in the existing definitions of detection from this perspective.

The Problem of Statistical Analysis with Nondetects

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Low-level concentrations of organic and inorganic chemicals are often reported to users as "nondetect" or "less-than" values. Concentrations are below the laboratory's reporting level (RL). Statisticians call these "censored data" -- observations reported only as below or above a threshold value. Regulatory guidance for the environmental community generally recommends using outdated methods for handling nondetects. These outdated methods produce estimates with high bias, or introduce signals that were not originally present in the data. The problems with existing recommendations are reviewed here. Better methods available for handling nondetects are discussed in the companion talk "Survival Analysis Methods for Interpreting Data With Nondetects" in this session, or in the textbook ***Nondetects And Data Analysis: Statistics for censored environmental data*** *(Helsel, 2005).*

Nondetects occur in a wide variety of disciplines, including air quality, water quality, astronomy, pharmacology, ecology, radiochemistry, toxicology, occupational hygiene, marine studies, geochemistry and medical chemistry. Long considered "second class data", nondetects have complicated the familiar computations of descriptive statistics, testing differences among groups, and the development of regression models. Within environmental sciences, the most common procedure continues to be substitution of one-half the reporting level for nondetects, even though this procedure has been known to be inadequate for almost two decades (Gilliom and Helsel, 1986). Recommended methods for handling nondetects are generally "old technology". Inaccurate statistics, poor and misleading regression models, and incorrect decisions to remediate (or not) result from these recommendations. There are better ways.

Computing the Mean, UCL95, and Other Descriptive Statistics

Current environmental guidance documents that address handling nondetects include the Technical Support Document for Water Quality-based Toxics Control, or TSD (USEPA Office of Water, 1991), the Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites (USEPA Office of Emerg. Remedial Response, 2002), the Addendum to the Interim Final Guidance for statistical analysis at RCRA sites (USEPA Office of Solid Waste, 1992), the Guidance for Data Quality Assessment: Practical Methods for Data Analysis (USEPA Office of Research and Dev., 1998), "Assigning Values To Nondetected/Non-Quantified Pesticide Residues in Human Health Food Exposure Assessments" (USEPA Office of Pesticide Programs, 2000), the Aquaculture Technical Development Document (USEPA Office of Water, 2002) and the RCRA Waste Sampling Draft Technical Guidance (USEPA Office of Solid Waste, 2002). Three methods are consistently recommended in these documents for computing descriptive statistics of data with nondetects. All three methods are 'old technology', exhibiting either bias or higher variability than other methods now available. The three methods are:

1. Substituting one-half the reporting level
2. The delta-lognormal (Aitchison's) method
3. Cohen's method

Substituting one-half the reporting level has been found by numerous studies to produce poor estimates. Helsel and Cohn (1988) found that it "represents a significant loss in information" in comparison to better methods. Singh and Nocerino (2002) found it to produce "a biased estimate of mean with the highest variability", and Lubin et al. (2004) show that it "results in substantial bias unless the proportion of missing data is small, 10 percent or less". The Office of Solid Wastes' RCRA guidance documents (1992, 2002) recommended substitution only when data sets contain fewer than 15% nondetects, in which case the method is "satisfactory". However, that judgment is not based on performance studies, but on verbal opinion. US EPA's Local Limits Development Guidance Appendices (USEPA Office of Wastewater Mgmt., 2004) breaks from this pattern by recommending against substitution methods. It recognizes that substitution results in a high bias when calculating the mean or standard deviation, with performance worsening as the proportion of nondetects increases.

An additional difficulty with substitution is that most data today contain values below multiple reporting levels. Levels may change over time, with differing dilutions of samples, because data were sent to multiple laboratories, or because methods for setting reporting levels have changed. Regardless of the cause, substituting a fraction of these changing levels for nondetects introduces a signal unrelated to concentrations present in the samples themselves. The signal represents the pattern of reporting levels, an artificial signal not present in the media sampled. False trends may be introduced, or actual trends obscured and go unnoticed.

The delta-lognormal method (also called the D-LOG, or Aitchison's method) was first proposed by Aitchison (1955), who applied it to economic data for which actual zeros were plausible. As applied to environmental data, the method models detected observations using a lognormal distribution while assuming all nondetects equal zero. The overall mean equals the mean of the detected values, multiplied by the proportion of detected values in the dataset $\bar{x} = \frac{n_d}{n}\,\bar{x}_d$. The mean of detected values is computed using the familiar formula for the lognormal distribution:

$\bar{x}_d = \exp\left[\bar{y} + 0.5 s_y^{\,2}\right]$, where y = ln ($x_d$), the natural logarithms of detected values.

The only difference between the delta-lognormal method and a simple substitution of zeros for all nondetects is in how the mean of detected values is computed. For simple substitution, this mean is computed as the sum of the detected values divided by n_d. Gilliom and Helsel (1986) found that the performance of the delta-lognormal method was essentially identical to that for zero substitution. Both methods had high errors. Yet the delta-lognormal method has continued to be recommended in guidance documents such as the USEPA's Guidance for Data Quality Assessment (USEPA Office of Research and Dev., 1998).

The Technical Support Document for Water Quality-based Toxics Control (USEPA Office of Water, 1991) modified the delta-lognormal method, though the same name was used. In the modified method, nondetects were assumed to fall at their reporting levels rather than at zero. This change produces the highest possible value for the overall mean, and underestimates the

standard deviation. As with substituting zeros, there is little difference between the TSD's modified method and substitution of the reporting levels for all nondetects. The modified method has the same primary flaw as substituting the reporting level – the values substituted introduce a signal due to changing reporting levels rather than to concentrations in the samples themselves. The poor performance of substituting the reporting level found by Gilliom and Helsel (1986) and subsequent authors is applicable to the TSD's modified delta-lognormal procedure. In addition, Hinton (1993) evaluated the modified procedure directly and found that it was outperformed by better procedures.

Cohen's method (Cohen, 1959) was based on maximum likelihood estimation (MLE). MLE requires more computing power than was available to most scientists of the late 1950s. So Cohen (1959) developed a lookup table of approximate coefficients to decrease the mean and standard deviation of detected observations, estimating the mean and standard deviation for the entire distribution. The coefficients were a function of the proportion of nondetects in the data set. Cohen's method assumed that data follow a normal distribution, and was developed for one censoring threshold (reporting level). Both assumptions are important limitations in how the method is applied today. Few modern data sets have only one reporting level, so data must be re-censored at the highest level before the tables are used. With example reporting levels of 1 and 10 units, all detected observations between 1 and 10 (and all nondetects) must be designated as <10 units prior to use of the tables. This loses information, introducing error. Also, today the lognormal distribution is considered a more realistic distribution for most environmental data than is the normal distribution. For such data, Cohen's method is computed using the logarithms of data, with estimates of mean and standard deviation of logarithms transformed back into original units. This transformation introduces a bias for data with few (<50) observations (Helsel and Cohn, 1988; Shumway et al., 2002)

Cohen's method is now totally unnecessary. Today, more accurate maximum likelihood estimation (MLE) solutions are possible with available statistical software. In particular, multiple reporting levels are easily handled by MLE software, in contrast to Cohen's method.

Testing Hypotheses

Less guidance has been published for testing differences among groups of data with nondetects than for estimating descriptive statistics. The most frequently recommended method is the test of proportions (also called contingency tables) (USEPA Office of Emerg. Remedial Response, 2002; USEPA Office of Solid Waste, 1992). This test is appropriate for data with one reporting level, though even there it loses information in comparison to better methods. The test places all data into one of two categories, below or above the reporting level, testing for differences between groups in the proportion of detected versus nondetected data. Information is lost on the relative ordering between detected values that is captured and used by other nonparametric tests such as the rank-sum test. To use the test of proportions on data with multiple reporting levels, values must be re-censored and reported as either below or above the highest reporting level. This loses a large amount of information in comparison to methods that handle multiple levels. The only advantages of the test of proportions are its simplicity, and its availability in familiar software.

In contrast, the most common method used by scientists is again to substitute fabricated values such as one-half the reporting level for nondetects, and run standard tests such as the t-test. Clarke (1998) demonstrated the significant errors produced by substituting numbers prior to running standard statistical tests. This process may produce signals that were not present in the original data, or obscure those that were. Using t-tests, Clarke tested small data sets with one reporting level. Substitution of reporting levels, or values ranging between 0 and the RL, produced inaccurate test results. The best results were obtained by first ranking the data (rankits) so that all nondetects were tied at the lowest rank. The subsequent t-test on the ranks approximates a nonparametric rank-sum test (Conover and Iman, 1981). Nonparametric tests such as the rank-sum test work very well for analysis of data with one reporting level (Helsel, 1990).

The rank-sum and Kruskal-Wallis tests are sometimes recommended for comparing data with single reporting levels (USEPA Office of Emerg. Remedial Response, 2002; USEPA Office of Solid Waste, 1992). These nonparametric tests compare whether one group generally produces higher observations than another. However, the CERCLA guidance (USEPA Office of Emerg. Remedial Response, 2002) states that the Kruskal-Wallis test should not be used when there are more than 40% nondetects. The reason for this recommendation is unclear -- there are no such limitations on nonparametric methods. The RCRA guidance addendum (USEPA Office of Solid Waste, 1992) makes the opposite recommendation – that standard nonparametric tests be used rather than the test of proportions. Differences in the high ends of the distributions, if present, will be picked up by nonparametric tests even at high censoring. Groups will be found to differ if their proportions of nondetects differ, even if overall proportions are high (Helsel, 2005). For example, statistically significant differences were found by the Kruskal-Wallis test (Helsel, 2005) between the distributions of trichloroethylene (TCE) concentrations within the three groups of Figure 1, even though approximately 90 percent of data are nondetects. Medium and high residential densities produce some high TCE concentrations, while the low density residential group does not.

The most importance weakness of standard nonparametric tests are they are not designed to deal with data censored at multiple reporting levels. Most environmental data today have been censored using multiple levels. Guidance on methods for testing data with multiple reporting levels has been lacking.

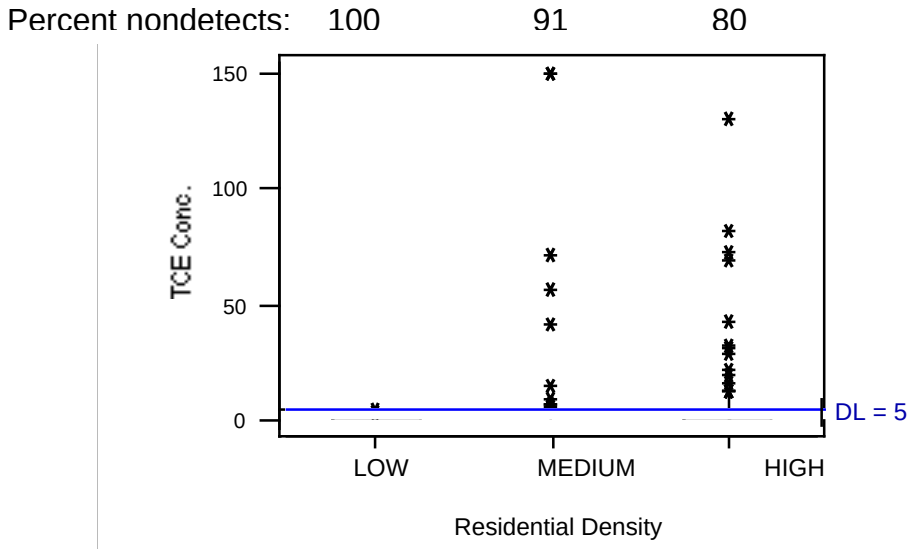

Figure 1. Censored boxplots of three groups with different patterns of concentration, as determined by the Kruskal-Wallis test.

Developing Regression Models

Regression equations are one of the foundations to interpreting environmental data. However, little guidance exists for developing good regression models that incorporate nondetects. Currently-used methods are dominated by substitution of fabricated values for nondetects.

Consider summer dissolved iron (DFe) data presented in Table 5 of Hughes and Millard (1988):

DFe:	20	<10	<10	<10	<10	7	3	<3	<3
Year:	1977	1978	1979	1980	1981	1982	1983	1984	1985

To determine whether there is a trend in dissolved iron over time, a regression of DFe (y-variable) versus Year (x-variable) can be computed and the slope tested to determine if it is significantly different from zero. One analyst might set nondetects to the value of their reporting levels, while another sets all nondetects to 0. The results for both are given below.

```
nondetects = reporting level
The regression equation is
DFe = 3508 - 1.77 YEAR

Predictor        Coef     SE Coef          T        P
Constant       3508.2       662.4       5.30    0.001
Year          -1.7667      0.3344      -5.28    0.001

S = 2.590       R-Sq = 80.0%     R-Sq(adj) = 77.1%


nondetects = 0
The regression equation is
DFeZero = 2215 - 1.12 YEAR
```

```
Predictor        Coef     SE Coef          T        P
Constant         2215        1627       1.36    0.215
Year          -1.1167      0.8211      -1.36    0.216

S = 6.360       R-Sq = 20.9%     R-Sq(adj) = 9.6%
```

When substituting the reporting level for all nondetects, the slope of DFe versus Year (–1.77) appears significantly different from zero with a t-test statistic of –5.28 and a p-value of 0.001. A significant trend of decreasing dissolved iron is declared. However when zeros are substituted for nondetects, the slope for Year (–1.12) is not significantly different from zero (p = 0.216), so no trend is found. The values for the intercept change by about one-third. The r-squared changes from 80 to 21 percent. Neither equation can be considered more valid than the other, based on underlying principles. Neither is definitive. With only the above evidence available, neither equation is necessarily correct. Even if both had produced the same result of non-significance, the choice to substitute values somewhere in-between these two could produce a significant test result. Clearly substitution produces inadequate information on which to base any decision.

Thompson and Nelson (2003) found that substitution of one-half the reporting level produced biased estimates of regression slope, as well as producing confidence intervals that were too small. Their study used simulations with consistently-defined levels. The errors they found were likely not as large as would be found in practice for environmental data, given the inconsistencies among laboratories in the determination of reporting levels. Even with their smaller errors, however, their study strongly advocated better methods than substitution for performing regression with censored data.

Guidance documents for environmental professionals have been silent on how to compute regression equations with censored data.

Summary

Guidance for interpreting environmental data with nondetects has been inadequate. Until the technology exists to report data with sufficient precision and unclouded by interferences, so that reporting levels are not required, scientists will be dealing with this issue. Given the importance, expense, and ramifications of environmental decision-making, substitution of fabricated values for nondetects cannot be defended. The failings of substitution are even more striking when considering the ready availability of better, more exact, and industry-standard methods for interpreting data with nondetects. These better methods are outlined in a subsequent talk.

References

Aitchison, J. J., 1955, On the distribution of a positive random variable having a discrete probability mass at the origin: *Journ. Am. Stat. Assoc*. 50, 901-908.

Clarke, J. U., 1998, Estimation of censored data methods to allow statistical comparisons among very small samples with below detection limit observations: *Environmental Science and Technology* 32, 177–183.

Cohen, A. C., 1959, Simplified estimators for the normal distribution when samples are singly censored or truncated: *Technometrics* 1, 217–237.

Conover, W.J. and R.L. Iman, 1981, Rank transformations as a bridge between parametric and nonparametric statistics: *American Statistician* 35, 124–129.

Gilliom, R. J., and D. R. Helsel, 1986, Estimation of distributional parameters for censored trace level water quality data, 1. Estimation techniques: *Water Resources Research* 22, 135–146.

Helsel, D.R. 1990, Less than obvious: Statistical treatment of data below the detection limit: *Environmental Science and Technology* 24, pp.1766–1774.

Helsel, D.R., 2005. Nondetects And Data Analysis: Statistics for censored environmental data. Wiley, New York 250 p.

Helsel, D.R. and T. A. Cohn, 1988, Estimation of descriptive statistics for multiply censored water quality data: *Water Resources Research* 24, 1997–2004.

Hinton, S., 1993, D Log-normal statistical methodology performance: *Env. Sci. and Technol*. 27, 2247-2249.

Hughes, J. P and Millard, S. P., 1988, A tau-like test for trend in the presence of multiple censoring points: *Water Resources Bulletin* 24, 521–531.

Lubin, J.H. et al., 2004, Epidemiologic evaluation of measurement data in the presence of detection limits: *Env. Health Perspect*. 112, 1691-1696.

Shumway, R. H., R. S. Azari, and M. Kayhanian, 2002, Statistical approaches to estimating mean water quality concentrations with detection limits: *Environmental Science and Technology* 36, 3345–3353.

Singh, A. and J. Nocerino, 2002, Robust estimation of mean and variance using environmental data sets with below detection limit observations; *Chemometrics and Intelligent Laboratory Systems* 60, 69–86.

Thompson, M.L. and K. P. Nelson, 2003, Linear regression with Type I interval- and left-censored response data: *Environmental and Ecological Statistics* 10, 221–230.

USEPA, Office of Emergency and Remedial Response, 2002. *Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites*. EPA 540-R-01-003, Wash. D.C.

USEPA, Office of Pesticide Programs, 2000. *Assigning Values to Nondetected/Non-quantified Pesticide Residues in Human Health Food Exposure Assessments*. Item 6047, Wash.

D.C.

USEPA, Office of Research and Development, 1998. *Guidance for Data Quality Assessment: Practical Methods for Data Analysis*. EPA/600/R-96/084, Wash., D.C.

USEPA, Office of Solid Waste, 1992. *Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities: Addendum to Interim Final Guidance*. Unnumbered document, Washington, D.C.
available at:
http://www.epa.gov/epaoswer/hazwaste/ca/resource/guidance/sitechar/gwstats/gwstats.htm

USEPA, Office of Solid Waste, 2002. *RCRA Waste Sampling Draft Technical Guidance*. EPA-530-D-02-002, Wash., D.C.

USEPA, Office of Wastewater Management, 2004. *Local Limits Development Guidance Appendices*. EPA 833-R-04-002B. Wash. D.C.

USEPA, Office of Water, 1991. *Technical Support Document For Water Quality-based Toxics Control*. EPA/505/2-90-001 Wash., D.C.

USEPA, , Office of Water, 2002. *Development Document for Proposed Effluent Limitations Guidelines and Standards for the Concentrated Aquatic Animal Production Industry Point Source Category*. EPA-821-R-02-016, Wash., D.C.

Survival Analysis Methods for Interpreting Data with Nondetects

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Low-level concentrations of organic and inorganic chemicals are often reported to users as "nondetect" or "less-than" values (censored data). Existing guidance for handling these data too often recommends methods that result in bias and inaccuracy. See the companion talk "The Problem of Statistical Analysis with Nondetects" for more details. Standard survival analysis methods of medical statistics, though conventionally applied to "greater thans", can also be applied to the "less-thans" of low-level environmental concentrations. Regulatory guidance for the environmental community has not yet incorporated these newer procedures. Here I review methods now available for improved handling of data with nondetects. More detail is found in the textbook ***Nondetects And Data Analysis: Statistics for censored environmental data*** *(Helsel, 2005).*

Nondetects occur in a wide variety of disciplines, including air quality, water quality, astronomy, pharmacology, ecology, radiochemistry, toxicology, occupational hygiene, marine studies, geochemistry and medical chemistry. Long considered "second class data", nondetects have complicated the familiar computations of descriptive statistics, testing differences among groups, and development of regression models. However, data censored as "greater thans" are routinely incorporated into statistical procedures in medical statistics through the methods of survival analysis. Survival analysis consists predominantly of parametric methods based on maximum likelihood estimation (MLE), and nonparametric methods based on Kaplan-Meier and related statistics. Both classes of procedures produce results of greater accuracy and precision than those commonly used in environmental sciences today. Applications of survival analysis to computing descriptive statistics, testing hypotheses, and development of regression models are surveyed here.

Computing the Mean, UCL95, and Other Descriptive Statistics

Survival analysis methods available for estimating descriptive statistics for data with nondetects include:

1. Maximum likelihood estimation (MLE), and
2. Kaplan-Meier

A third method (Regression on Order Statistics, or ROS) has also been found useful for computing descriptive statistics on censored data.

MLE for censored data can be performed using readily-available survival analysis software The method iteratively solves a likelihood equation to find the values for mean and standard deviation that are most likely to have produced the observed data, both nondetects and detected

values. A specific shape of the data distribution, such as the lognormal, must be chosen to begin the process. The fit is to both the values for detected observations and to the proportion of data falling below each reporting level. Maximum likelihood works best when there is ample data (somewhere around 50 detected values), and where there is sufficient evidence for the scientist to believe that the assumed distribution fits the data well (Helsel and Cohn, 1988; Singh and Nocerino, 2002; Shumway, et al., 2002). Estimates of mean, standard deviation, and percentiles of the fitted distribution are produced.

Kaplan-Meier (K-M) is the standard procedure within the medical sciences for analysis of censored data. K-M was designed to incorporate data with multiple reporting levels, and does not require specification of an assumed distribution – it is a nonparametric method. It estimates the percentiles, or cumulative distribution function (cdf), for the data set (Helsel, 2005). K-M is a counting procedure. Starting at the largest detected value and working down the data set, a percentile for each detected observation is assigned using the number of detects and nondetects above and below each observation. Percentiles are not assigned to nondetects, but nondetects affect the percentiles calculated for detected observations. A step-function plot of the cdf called the "survival curve" is produced, giving a picture of the shape of the data set (see Figure 1). The mean is computed as the area under the survival curve. The K-M procedure has been used primarily for data with "greater-thans". To apply it to the "less-thans" of environmental sciences, data must currently be transformed ("flipped") by subtracting each observation from a large constant (Helsel, 2005) before performing K-M. Flipping data is necessary only because commercial software is currently coded to handle only greater-thans. Flipping data may become unnecessary in future versions of software, as K-M becomes more widely used for analysis of "less-than" data.

Regression on Order Statistics (ROS) fits a regression line to a probability plot. The line is computed using detected observations, plotted as points on the graph, while plotting positions (percentiles) are adjusted for the number of nondetects present in the data set. Nondetects censored to multiple reporting levels can be incorporated by ROS (Helsel and Cohn, 1988). The slope and intercept of the regression line are 'parametric' estimates of the mean and standard deviation, respectively. These are the values output from most statistical software, and some studies have chosen to use these parametric estimates. However, they do not perform as well as those produced by MLE. Instead, a 'robust' version of ROS has been used (Helsel and Cohn, 1988 where it is called "MR"; Shumway et al., 2002) to avoid the small-sample bias incurred when estimates of descriptive statistics in log units are retransformed back to units of concentration. In this robust form, descriptive statistics are directly computed using the detected observations, combined with imputed data for nondetects taken from the lower end of the ROS regression line. Robust ROS estimates of mean and standard deviation have been shown to perform better than MLE for smaller sample sizes ($n<50$) or when the data do not fit the assumed distribution well (Helsel and Cohn, 1988; Shumway et al., 2002). ROS also has the added visual advantage of a corresponding probability plot, providing a clear visual picture of the shape of the data distribution. ROS methods have been incorporated into recent environmental guidance documents, including those of USEPA (USEPA, Office of Wastewater Mgmt., 2004) and the State of Colorado (Colorado Water Quality Control Division, 2003).

These three methods for computing descriptive statistics (MLE, K-M and ROS) offer increased accuracy and precision over methods more often cited in environmental guidance documents. All three handle multiple reporting levels with ease. None of the three involve fabricating data such as one-half of the reporting level for nondetects.

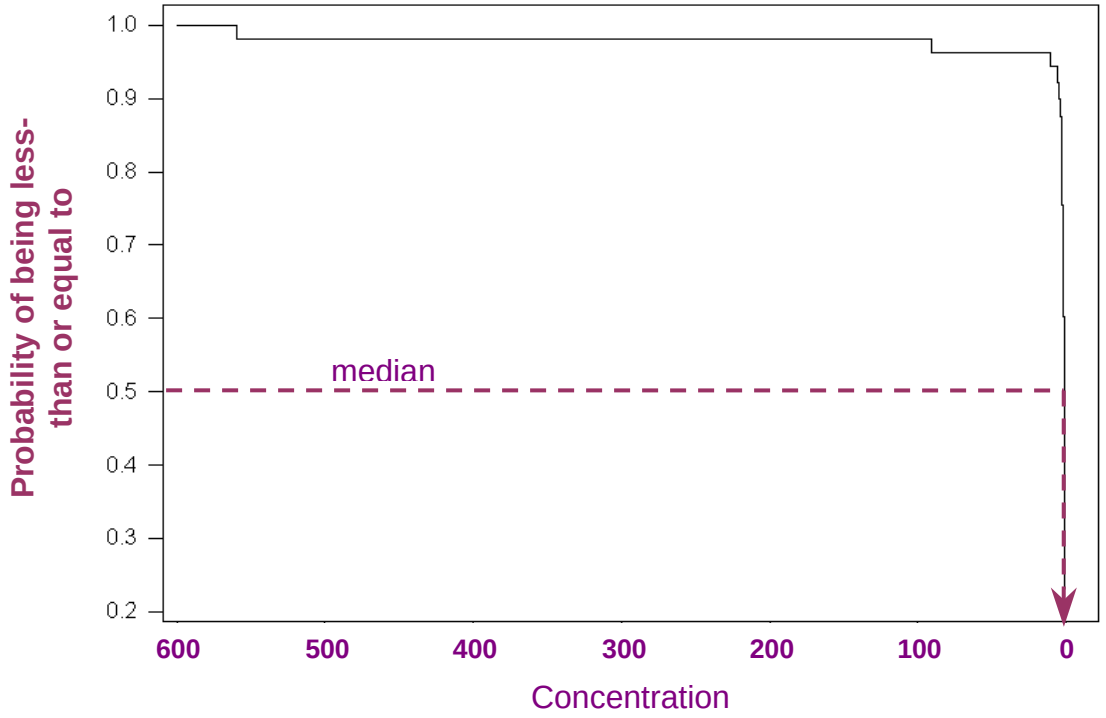

Figure 1. A Kaplan-Meier survival curve (cdf) for concentration data (Helsel, 2005). Note that the concentration scale increases from right to left.

Testing Hypotheses

Both parametric and nonparametric methods are available for testing differences in means or medians of groups containing data with multiple reporting levels. These methods have not yet been adopted by environmental guidance documents. Both types of tests may be found within survival analysis sections of commercial statistical software. Parametric methods use maximum likelihood to perform tests equivalent to the t-test and analysis of variance (ANOVA). No substitution of fabricated values is required for data below one or more reporting levels. Instead, likelihood ratio tests determine whether splitting the data into groups explains a significant proportion of the overall variation. If so, the means differ among the groups.

Nonparametric methods go by the name “score tests”. Millard and Deverel (1988) pioneered the use of nonparametric score tests for censored environmental data in 1988. These tests, sometimes called the “Generalized Wilcoxon” or “Peto-Prentice” tests, extend the familiar Wilcoxon rank-sum and Kruskal-Wallis tests to data with multiple reporting levels. No values are substituted. No re-censoring is necessary. The tests compare the cdfs among groups of data, determining

whether their survival curves (percentiles) differ. Even if lower percentiles are indistinguishable because they are all nondetects, differences in higher percentiles will be seen if they are significant. The major impediment to the routine use of score tests has been that commercial software is coded to recognize only greater-thans. Environmental data with less-thans must first be flipped (Helsel, 2005) prior to using currently available software for these tests.

Figure 2 shows the percentiles of trichloroethylene (TCE) concentrations for data in three groups of residential density. The data were censored at three different reporting levels, 1, 2 and 5 micrograms per liter. The Generalized Wilcoxon test produces a p-value of 0.0003, finding that these three groups do not all have the same distribution. This is seen in Figure 2 as differences between the upper ends of each curve. The upper percentiles of the Low density group remain low in concentration, while the Medium and High density groups have higher concentrations. Even with three reporting levels and 90% censoring overall, the Wilcoxon score test discerns that at least one group is different from the others.

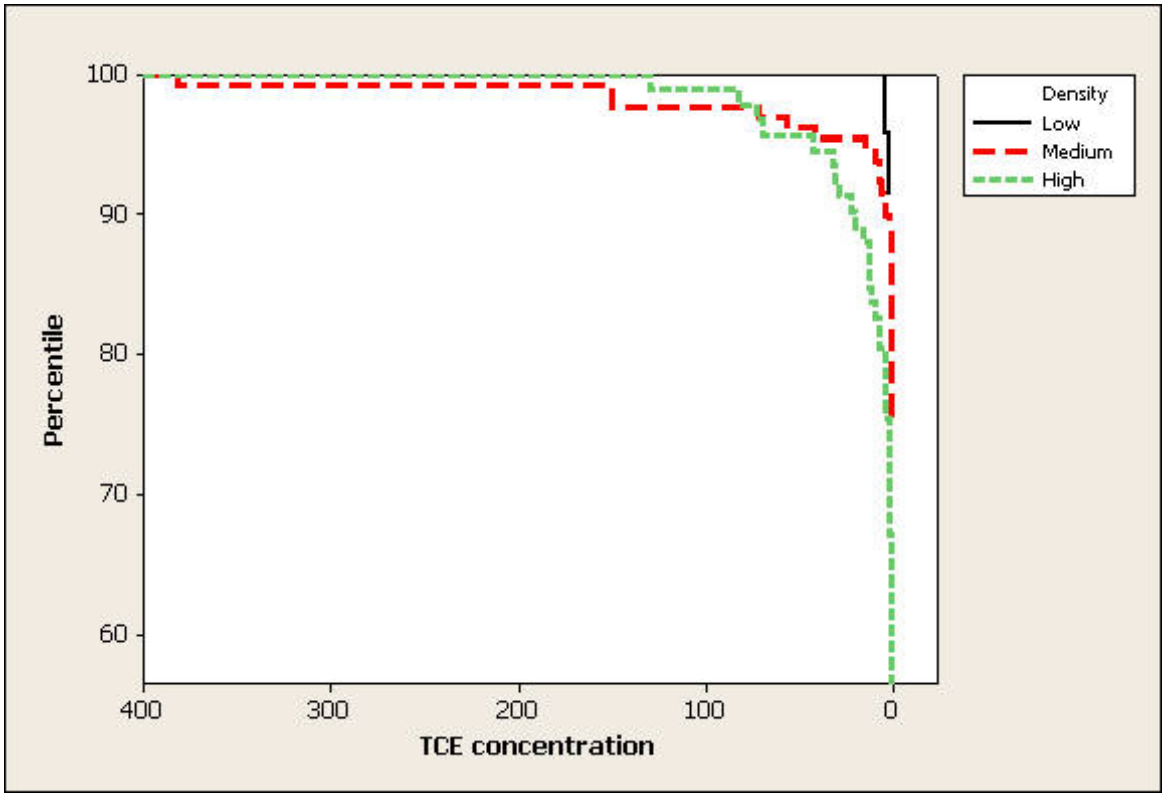

Figure 2. Survival function plot of TCE concentrations in ground water for three groups: Low, Medium and High Density residential areas (modified from Helsel, 2005).

Developing Regression Models

Methods for performing censored regression are readily available in commercial software, but have not made their way into guidance documents, or routine use, by environmental

professionals. Censored regression requires no substitution of fabricated data, avoiding the pitfalls of currently-used methods.

Slopes and intercepts for censored regression are fit by maximum likelihood rather than least-squares. This allows direct incorporation of nondetect data into model building. Nondetects are input using "interval endpoints" stored in separate columns (Helsel, 2005); a low endpoint, usually at zero, and an upper endpoint of the reporting level. Detected observations have the same value for both endpoints. Data are considered to fall somewhere between the lower and upper endpoint of each observation. Likelihood ratio tests rather than the familiar partial t- and F-tests determine significance of each explanatory variable. To determine whether an explanatory variable belongs in the regression model, likelihood statistics for models with and without that explanatory variable are compared. If there is little difference in how well these models fit the data, the p-value for that variable is high and the variable can be deleted from the model. If the variable influences the model, the p-values will be small and the variable retained. Likelihood correlation coefficients are also available; censored method analogs to most familiar regression statistics can be computed.

For the dissolved iron concentrations of Hughes and Millard (1988) used for illustration in the companion article, regression equations for left-censored data are computed by MLE. The result is a unique solution, with a defensible test for whether or not the slope coefficient differs from zero. MLE produces estimates for slope and intercept that are best-fit parameters, given censored data and the assumptions of normality and linearity. The slope for Year (–1.73) has a p-value of essentially zero; a linear downtrend in summer iron concentrations is found to occur over this time period.

Coefficients estimated by MLE
DFe = 3426 - 1.73 YEAR
Estimation Method: Maximum Likelihood
Distribution: Normal

Regression Table

Predictor	Coef	Standard Error	Z	P	95.0% Normal CI Lower	Upper
Intercept	3426.1	859.3	3.99	0.000	1741.9	5110.2
Year	-1.7260	0.4337	-3.98	0.000	-2.5760	-0.8760
Scale	3.1083	0.9785			1.6771	5.7607

Log-Likelihood = -13.184

One advance in the treatment of censored data over the last 15 years has been in nonparametric models for fitting straight lines to censored data. Lines based on Kendall's tau correlation coefficient have been applied to data in astronomy, where light intensities often include "less-than" values (Akritas et al., 1995). These nonparametric lines fit a median surface to data, appropriate whenever a 'typical' relation between y and x is desired, rather than the mean surface of parametric regression. Outliers have much less influence on the Kendall-based lines. Another advantage of the Kendall procedure is that, unlike lines using parametric MLE, an equation can be fit when both of the x and y variables are censored. Examples of fitting these Kendall lines to environmental data have been given in Helsel (2005).

Summary

Methods for interpreting environmental data with nondetects can be directly borrowed from existing survival analysis methods for handling data with greater-thans. Guidance documents for environmental professionals have not yet incorporated these methods. Until the technology exists to report data with sufficient precision and unclouded by interferences, so that reporting levels are not needed, scientists will be dealing with this issue. Given the importance, expense, and ramifications of environmental decision-making, survival analysis methods should now be used to provide definitive solutions for the analysis of censored environmental data.

References

Akritas, M.G. et al., 1995. The Theil-Sen estimator with doubly censored data and applications to astronomy. J. Am. Stat. Assoc. 90, 170-177.

Colorado Water Quality Control Div., 2003. *Determination of the Requirement to Include Water Quality Standards-Based Limits in CDPS Permits Based on Reasonable Potential: Procedural Guidance*. Denver.
Located at http://www.cdphe.state.co.us/wq/PermitsUnit/wqcdpmt.html#RPGuide

Helsel, D.R., 2005. Nondetects And Data Analysis: Statistics for censored environmental data. Wiley, New York 250 p.

Helsel, D.R. and T. A. Cohn, 1988, Estimation of descriptive statistics for multiply censored water quality data: *Water Resources Research* 24, 1997–2004.

Hughes, J. P and Millard, S. P., 1988, A tau-like test for trend in the presence of multiple censoring points: *Water Resources Bulletin* 24, 521–531.

Millard, S.P. and S. J. Deverel, 1988, Nonparametric statistical methods for comparing two sites based on data with multiple nondetect limits: *Water Resources Research* 24, 2087–2098.

Shumway, R. H., R. S. Azari, and M. Kayhanian, 2002, Statistical approaches to estimating mean water quality concentrations with detection limits: *Environmental Science and Technology* 36, 3345–3353.

Singh, A. and J. Nocerino, 2002, Robust estimation of mean and variance using environmental data sets with below detection limit observations; *Chemometrics and Intelligent Laboratory Systems* 60, 69–86.

USEPA, Office of Wastewater Management, 2004. *Local Limits Development Guidance Appendices*. EPA 833-R-04-002B. Wash. D.C.

Assessing the risk associated with mercury: using ReVA's webtool to compare data, assumptions and models

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The problem of assessing risk from mercury across the nation is extremely complex involving integration of 1) our understanding of the methylation process in ecosystems, 2) the identification and spatial distribution of sensitive populations, and 3) the spatial pattern of mercury deposition. Unfortunately, both our understanding of the processes involved, and the availability of data to make this assessment are currently imperfect, yet there are effective ways to make use of data and information that currently exist.

ORD's Regional Vulnerability Assessment (ReVA) Program was designed to develop and demonstrate methods to use existing data and models to inform environmental decision-making regarding broad-scale comparative and cumulative risks. Focusing on the integration of available spatial data and model results, ReVA has developed a web-based Environmental Decision Toolkit (EDT) that is the perfect vehicle for evaluating alternative ways of assessing the risks associated with mercury deposition from energy generating units and subsequent methylation into the more toxic methylmercury (MeHg) that accumulates in fish tissue. Given that there is no obvious "right" way to assess the risk from MeHg, a toolkit with the flexibility to consider and compare alternative data, model inputs, and assumptions, and alternative ways to combine these inputs into indices of relative risk will allow a broader understanding of where the greatest uncertainties lie and where there is agreement among data and methods.

The EDT is a statistical toolkit that displays information spatially. The advantage of using a statistical package over a GIS is that it allows rapid reanalysis of data such that different combinations of variables can be displayed and compared quickly. This makes it ideal for problems that have a great deal of uncertainty or where a number of "what if" scenarios might be explored. Within the Hg-EDT:

- the raw data can be viewed and explored,
- choices can be made as to which data or model results are used in determining overall risk when multiple options exist,
- different weights for influential parameters can be set for estimating a methylation potential index,
- comparisons can be made between estimated values and monitored data, and
- distributions of sensitive populations, estimated indices of methylation potential, and estimated mercury deposition can be integrated into relative rankings of risk from mercury generated from EGUs.

Status and Changes in EPA Infrastructure for Bias Traceability to NIST

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Abstract

Changes have been and are occurring in a number of the parts of the EPA QA infrastructure authorized and established by EPA's ORD-QA staff in RTP and DC in the 1980's to characterize and promote traceability of EPA ambient air monitoring data to NIST standards. EPA's benchmark Quality Assurance (QA) programs support the comparability of the calibrations that all reporting organizations use to assign values to the otherwise undefined instrumental signals that air monitors provide as the basis of the data reported to EPA for compliance and other uses.

This discussion will address status of changes in the EPA's National Performance Audit Program (NPAP) for Ambient Air Criteria and other Pollutants, the EPA's Standard Reference Photometer (SRP) Program for traceably standardizing ambient ozone measurements, and the EPA Protocol Gas Verification by an independent, EPA-approved, third party. In 1996 EPA OAQPS agreed to take the programs over from EPA ORD, to the extent allowed every year by resources/ priorities.

The transition of the NPAP-mailed and back-of-the-analyzer(BOA-) only,) into the National Performance Evaluation Program (NPEP = NPAP, mailed/BOA, station operator performed +PEP+TTP))has continued in 2004-2005. Summaries of TTP and mailed Regional PEs, first time ever EPA (~10) tow vehicle and national TTP(2) training sessions and certification and Regional TTP vs State TTP program PE, multi-Regional TTP Lab Sharing, and other implementation trade-offs and approximate costs are discussed.

The mobile laboratories' flexibility of design addresses the need to acknowledge that monitoring technology develops and evolves, and therefore so does the need for audit equipment, methods, and infrastructure support. NPEP TTP PEs have been conducted by 5 EPA Regions, on about 181 analyzers at about 127 sites in 25 states, in FY04. Expect TTP PEs in 9 regions in FY/CY05.

The SRP network of 10 NIST manufactured and certified systems are deployed, based, and operated in 8 of the 10 EPA Regions. They are compared to NIST SRPs using a stationary SRP based in RTP, and a traveling SRP in Las Vegas (LV), are operated by EPA Regions and staff with one exception- the Region 9 SRP has been operated by CA ARB. In the last 4 years, the network has undergone two upgrades- except for one still needing the second- and can now automatically perform the documented SRP vs SRP procedure and record the generated data used for certifying Regional vs. the LV SRP, and vs. primary and/or transfer standards from state and local agencies, and approved EPA contractors.See latest SRP Location list and 2004 Annual SRPvsSRP Certification Report on www.epa.gov/ttn/amtic/srpqa.

After 1996, the ORD's EPA Protocol Gas Verification Program program was not continued. EPRI (ca.1998), and then EPA (2003), in response to complaints from the user communities, each performed an additional blind sampling study, and found that, without the program, significant problems, across pollutants, had again occurred. Although the sample size of the original program was small and inexpensive, vendors paid attention- for very low cost, results improved over the 4-5 years of the program. EPA is therefore looking into a vendor-funded, EPA-approved, 3rd party-operated, blind sampling, publicly-reported verification program.

INTRODUCTION

This discussion will address status and changes in the EPA's National Performance Audit Program (NPAP) for Ambient Air Criteria and other Pollutants, the EPA's Standard Reference Photometer (SRP) Program for traceably standardizing ambient ozone measurements, and the EPA Protocol Gas verification by an independent, EPA-approved, third Party.

Changes have been and are occurring in a number of the parts of the EPA infrastructure authorized and established in the 1980's to characterize and promote traceability of EPA ambient air monitoring data to NIST standards, the basis of the centralized, comparable accuracy of data in the USA. These benchmark Quality Assurance (QA) programs support staff training and evaluation of the comparability of the calibrations that all reporting organizations use to assign values to the otherwise undefined instrumental signals that air monitors provide and are the initial basis of the data reported to EPA for compliance and other purposes.

Importance of the Functions of the Traceability Infrastructure

The Traceablity infrastructure has two important functions. The first role is to give EPA Regional oversight managers a handle on S&L proficiency, especially when used in combination with TSAs. Second, probably the greatest value of the NPAP, SRP, and Gas Protocol Verfication is to provide state and local agency managers with an independent benchmark tool to check the cost effectiveness of their ongoing operator training, procedure review, data validation, equipment maintenance, and calibration standard recertification activities in their organization.

These training and benchmark roles of the comparability infrastructure verfication tools (including systems audits) are especially important for two critical reasons:
1) The turnover of government environmental positions such as field operators and lab analysts in ambient air monitoring is normally a problem, but it has been escalating around the country as the Clean Air Act anniverary enters its 35th year, as well as because of national priorities.
2) The national level benchmark is important because 40 CFR Part 58, does not provide any other independent mechanism for determining how well agencies are doing in carrying out the requirements for the quarterly reporting of annually required, agency-funded audits. In addition,it is becoming more important as the number of sites used to characterize an area goes down (network size decreases), as recommended by the OAQPS National Air Monitoring Strategy, especially at NCOR level 2 sites, and in particular at level 2 locations for Trace (Precursor) Gas analyzers, and at Air Toxics and other speciation sampler/anlyzer locations.

Background/Status of NPAP

Since 1979, participation in the NPAP has been a QA requirement (40CFR part 58, appendices A, B, and C). Devices or materials have been provided as single blind samples used to evaluate the proficiency of the performance of EPA-required methods by the state local, or private monitoring station operators (and their equipment, standards, procedures, management,etc.). Some of the audits are of lab proficiency only, and some test field sampling and lab analyses and reporting. All audits are performed by the audited agency staff, usually *by* the station operator. All audits are provided by a single EPA audit support contractor. A listing of all the sites that have received mailed NPAP audits for ozone, CO, SO2, and NO2, and PM10 SSI/HiVol, from

1989 through 2003, as of March 2003, is provided at the EPA website at *www.epa.gov/ttn/amtic/npaplist*, in 2 parts (1989-1993, and 1994-2003).

As monitoring equipment used in the field have evolved from wet chemistry to continuous methods, so have the audit methods. Unfortunately, recognition of and provision for this evolution has not been built into the regulations or the supporting funding mechanisms.

RTP QA Changes-ORD to OAQPS

EPA's Ambient Air QA program started changing organizationally in 1996 when EPA ORD divested itself of its QA service programs and EPA OAQPS agreed to take over, as well as it could, depending every year on resources allocated and mission priorities.

NPAP Changes-Creation of PEP and Then NPEP

The particulate portion of the NPAP started changing with the addition in 1999 of portable, collocated, PM2.5 samplers, delivered, operated, retrieved and reported by a nationally coordinated, regionally based, EPA contractor. This program was first approved following many months of communications and eventual agreement between U.S. EPA OAQPS and almost all of the state and local ambient air monitoring agencies. The program is funded with State and Local agency Grants (STAG, 103 type), and is called the Performance Evaluation Program (PEP). Documents and reports of this program are available through the website for ambient monitoring.The website's URL is: http://www.epa.gov/ttn/amtic, at the qaqc\npepqa, and the ...amtic\pm2.5 and other ... /amtic menu choices on the amtic home page.

An effort was started in 2001 to improve the non-PM2.5 NPAP by combining it with the PEP, as NPEP, by adding a system of Regional mobile audit laboratories. These laboratories are each based in an EPA Region, as is the PEP program. Currently 6 mobile laboratories have provided laboratory quality audit gases verified at the audit site, and then delivered through the sampling inlet, or probe, and multi-instrument sampling manifold of the audited station. A general description of the TTP Mobile Labs' trailer, tow vehicle, tow safety features and procedures are provided, along with a few example pictures, at the EPA website at www.epa.gov/ttn/amtic/ambient/qaqc/trailer.pdf. Many more pictures and details are available on request.

Most audits in the US, including the mailed NPAP audits and the agencies' own quarterly reported audits, are delivered just to the back of the audited analyzer, bypassing station inlet, manifold, and connecting tubing. The model for the EPA Mobile Performance Evaluation (PE) Laboratories is the California Air Resources Board's (CARB's) Through-the-Probe (TTP) Mobile Audit Program. It has been in operation for about 20 years, and is documented on the CARB website. The SOP for the CARB TTP program is included as Appendix in the EPA QA Handbook, Vol II, Part 1, which is posted on the AMTIC website. The EPA Compendium of 11 Mobile TTP PE SOPs is a final draft that has been expanded and revised a number of times as the author and the network of Regional EPA and contractor operators and managers became more experienced with the operation and maintenance of the systems. It has been in review by the operators and managers since the last training session and certification, in Las Vegas,NV in December of 2004. It will be posted on the www.epa.gov/tnn/amtic/npaplist, where the mailed program QA project plan and SOPs are already listed, probably by the time of the meeting.

There are a number of important technical and quality differences between the existing mailed EPA NPAP and the new EPA NPEP Mobile TTP PE programs' capabilities and features. The new EPA TTP systems are transported, delivered under very favorable environmental conditions, operated and reported by trained 3rd party staff, completely independent of the agency being audited, have concentrations verified just before they are provided, having results available before leaving the site, use the best, latest, and highest quality equipment. They have the capacity to accurately provide sufficient volume for multianalyzer sampling stations with sampling flow rates of 15-30 lpm.. The mailed NPAP equipment has to be shipped. Therefore it is as compact and low in weight as possible, for lower shipping costs, more rugged, inexpensive, easily maintained, and therefore potentially less sensitive (precise and/or accurate) as hand-carried equipment. The quality of the delivery of the mailed devices is less than that possible with the mobile TTP system, but it may be adequate for the level of accuracy needed in particular sampling station circumstances.

Some situations are not feasible and/or not cost effective for the Mobile lab PE. Until the mobile lab components are made as portable as the mailed or PEP PE equipment, the EPA needs to ensure the availability of some minimum level of the mailed progam, along with the mobile lab systems. Examples of conditions requiring this resource be retained are sampling stations in: islands, mountains, sky scrapers, high theft inner cities, off-road (some tribal and/or other rural), far northern, cold climate locations.

The biggest cost benefit tradeoff is that it **costs more per audit/PE for the TTP system** than for the mailed system, all costs being included, but the Mobile lab comparison is very much more timely-same day- and meets the independence criteria for quality assessments more completely than the mailed program. The Mobile system's accuracy is also significantly greater than the mailed system's. As measured concentrations get lower, as trace level concentrations become more important, ,and each analylzer's results become more important(due to ther being fwere analyzers per network) , this greater accuracy will allow greater confidence in reported data, and in theablity to troubleshoot problems on the spot, when discrepancies arise.

Mobile Lab Designed Flexibilty/Multi-Use Capabilty

The mobile laboratories are designed to allow transport and deployment of the PM 2.5 devices, as well as other audit equipment, and of emergency/hazardous air sampling, of short duration, when Regional priorities dictate. For example, the roof sampling platform feature, with collapsible guardrails and associated roof duplex receptacles, is currently on three of the six mobile labs. The flexibility is enhanced by the expanded or expandible capacity of the data logging system, digital connectivity, flexibly designed and shock-mounted instrument racks, high capacity zero air generator, UPS-PLC system and power source system option features. This flexibility of design also addresses the need to acknowledge that monitoring technology develops and evolves, and therefore so does the need for audit equipment, methods, and infrastructure support.

Performance Accomplishments in 2004:Transitional Implementation

The first year of field work got started halfway into 2003. Some unresolved symptoms were noted independently by each of the 3 Regional operators, and worked around. The Region 6 and 7 each visted 11sites, mostly doing one analyzer PE at each site, often ozone, and doing a

number in each case of the 3 blended gas PEs. Region 5 did 2 sites. Only Region 6 did a few PEP + TTP PE trips.

Last year (2004) was very active, especially a few months after our first ever EPA and ESAT contractor operator network SOP Compendium review and combined lecture training /written exam and hands-on training and exam, in Las Vegas in May. The training was cost effective, as it was added to a PEP Certification training session. The logistics were very difficult because of the combined training agendas. The rewards of the daily maximum effort by the EPA and contractor participants were probably priceless- unattainable without the live, in person combined efforts of the group, with 2 mobile labs to work on, with the very helpful support of the EPA ORIA TAMS and Air Group staff support. The format was in the same general style as has been established for the PEP certification Field and Laboratory Scientist training.

In the months before the training session, 3 more mobile labs had been delivered to 3 more Regions and tried out at the home bases. At the training, the common flow system symptomatic problem was diagnosed and a solution found for the 2 mobile labs at the training session. The EPA and experienced ESAT operators all saw the diagnosis and working solution, and called the EPA diagnostician/operator when they arrived back at their home bases. They then all implemented appropriate adjustments to their own systems, and tried them out, successfully. The results were, subsequently, a fast-paced implementation of their 2004 TTP PE plans, as seen in the table and chart below.

Region(R)	**O3 PEs**	**CO PEs**	**SO2 PEs**	**NO2 PEs**	**TOT#/R**	**$$**
4	**24**	**2**	**6**	**1**	**33**	**~$40K***
5	**32**				**32**	
6	**22**	**8**	**6**	**8**	**44**	**~$40K***
7	**14**	**1**	**3**	**1**	**19**	
9	**32**	**13**	**4**	**9**	**58**	**~$40K***
TOTAL#	**124**	**24**	**19**	**19**	**186**	**0**

*= 33+44+58=135 Pes/$120K; ~ =

Planned Communication: Cost-Benefit Data for the Regional Mobile Lab TTP PEs
Summaries of regionally-based TTP audit results and program cost data collected from CY 2004 activities will be communicated to the EPA Regions and to the state and local agencies. These agencies will be asked, based on this information, to agree to request 103/105 grant funds to pay not just for the EPA PEP audits, as is done now, but also for the NPEP TTP audits. This approach was based on the feedback obtained in conference calls in 2001 with EPA Regional representatives, regarding improvements needed and desired in the NPAP, and at a STAPPA/ALAPCO meeting in Chicago, in May, 2001. Attendees agreed that, in concept, combination of the mailed NPAPand independently delivered PEP programs is a more cost-effective use of the NPAP and PEP-ESAT funds than is now allowed with the separately operated and funded programs. Before agreeing to request the combination, attendees wanted to see the results of pilot of the program.

Net NPAP/NPEP Funding Status, Costs, and Changes

The cost of providing the equipment for the first four new regional systems initially came from a one-time OAQPS NPAP improvement initiative fund of $375,000. The rest of the funds, needed for both the remaining equipment and the contract labor to operate and maintain the current total of 6 systems, has come from the contract S&T funds that have been provided by OAQPS in 2002-2004. The total contractor labor and associated O&M service costs have, over the first few yrs of operation, indicate a per analyzer cost of approx. $1.2K, or perhaps $1.5-$2k for an average of a 2 analyzer/site trip. The costs per analyzer and TTP trip are lower if the trip does a full set of PEP PEs in a week, and just adds the cost of the TTP part. The cost in each Region is always higher at the beginning, due to learning-curve.In each case, decreases in time to do an TTP PE are observed. The first TTP PEs have been TTP only, and therefore somewhat higher in cost. The total equipment cost of the 6 mobile labs has been about $700K(about $105K for the Trrailers, and $160K for the 1 truck. Assuming 5-7 years lifetime, 20-28 site trips/year, that adds about $500/trip to replace the trailer systems, and $1K/site trip to replace the trucks. The Major problem is that costs in the Regions have been estmated without replacement costs. Using EPA program funds, we cannot accrue replacement funds, Therefore, we must have the 103 or 105 grant funds used to fund these programs.

The number of NPAP mailed audits that the 10 Regions had become used to receiving, without more than the agency cost in performing the audits, has dropped drastically. This reduction had already started before the Regional TTP system development started, as a result of a reduction in NPAP contract funds that started in 1999, due to competing program priority needs, and has continued since then. The current NPEP funding is used to operate both mailed and TTP options. As the 6 Regional PEP+TTP(NPEP) systems, and the remaining complementary mailed NPAP program, show what they can do, for the funding amounts they have been given, we expected the number and quality of audits to increase to a more effective level, starting during the remainder of 2004 (after the May Training sessions).

The Table and chart below, "US SLAMS/PSD Ozone Monitors Audited by NPAP," show the changes for ozone, from 1998, the last year that was similar in funding and resulting service delivery to the previous 10 years, through 2004.

US SLAMS/PSD OZONE Monitors Audited by NPAP (as of 3-24-05)

Year	**No. of Samplers Audited/** No. Agencies (=Shipments)	**No. of Audits Requested**[1]/ No. of Agencies Requesting
1998	**686**/188	**727**/188
1999	**542**/184	**674**/201
2000	**352**/80	**692**/202
2001	**183**/55	**623**/164
2002	**205**/57	**544** /136

[1]Annual requests by Agency for NPAP audits

2003	(137 mailed + 22 ttp) = **159**/29	**533** /132
2004	(54 mailed + 124 ttp) = **178**/17	**463**/114
2005	0/3	**386**/102

EPA SRP Network Status and Changes

The EPA's SRP network of 11 NIST-manufactured and certified systems are deployed, based, and operated in 8 of the 10 EPA Regions. They were coordinated (certified as traceable to NIST) initially by the relatively standard combination of a stationary and a traveling SRP, both based in RTP. Currently the primary (coordinating, traveling) SRP is based in Las Vegas. The network of Regional SRPs has, all along, and is currently operated by EPA Regional staff, with one exception. The EPA Region 9 SRP has been operated by CARB. Now Region 9 has an SRP that will be used to back up the CARB support, given budget uncertainties, especially to nearby states and Regions, and in support of the new Region 9 Mobile TTP PE Lab program.

In the last 4 years, the network has undergone one upgrade, and is almost done with the second. Each change had improved both hardware and software. Those SRPs that have successfully had both upgrades are able to do what they could not do before, which is to automatically perform the documented SRP procedure and record the generated data used for certifying itself against the coordinating SRP, and to certify primary and/or transfer standards from state and local agencies, and approved EPA contractors. These upgrades have brought the systems up to date with the improvements of newer hardware and software that have been included in the systems assembled since the last EPA SRP was made in1989.

NIST STANDARD REFERENCE PHOTOMETERS

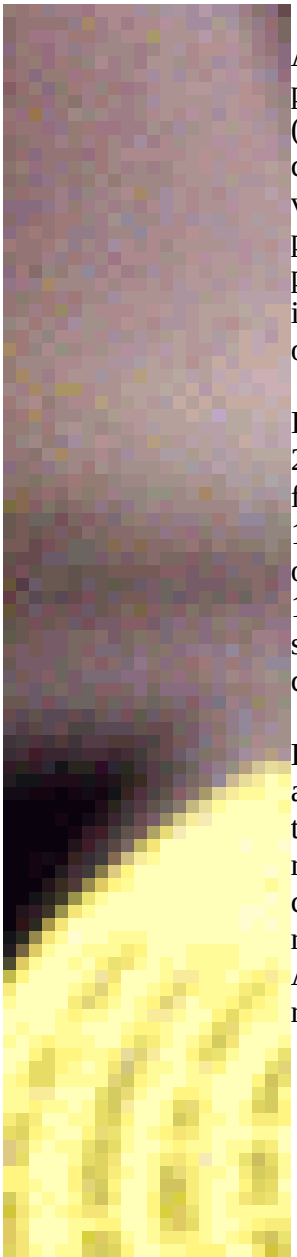
SRP#	COMPLETION DATE	LOCATION	ORGANIZATION
0	Aug.27, 1985	Gaithersburg, MD	NIST ("Backup")
1	Feb. 9, 1983	Raleigh, NC	EPA (ORD Lab; "Backup")
2	Feb. 9, 1983	Gaithersburg, MD	NIST ("Primary")
3	Aug. 23, 1983	Edison, NJ	EPA Region 2
4	Sep. 16, 1983	Sacramento, CA	EPA Reg. 9 (CA ARB)
5	March 20, 1985	Houston, TX	EPA Region 6 (Lab)
6	March 7, 1985	Chicago, IL	EPA Region 5
7	Jan. 23, 1986	Las Vegas, NV	EPA ORIA ("Primary")
8	Feb. 11, 1986	Denver, CO	EPA Region 8
9	May 6,1987	Lexington, MA	EPA Region 1 (Lab)
10	Nov. 4, 1987	Athens, GA	EPA Region 4 (Lab)
11	Sep. 25, 1987	Nyköping, Sweden	IAER
12	July 5, 1988	Toronto, Canada	MOEE
13	Jan. 31, 1989	Kansas City, KS	EPA Region 7 (Lab)
14	June 4, 1993	Bern, Switzerland	OFMET("Primary")
15	Oct. 20,1993	Dubendorf, Switz.	EMPA
16	Oct. 21, 1994	Ottawa, Canada	Env. Canada
17	Dec. 9, 1994	Prague, Czech Rep.	CHMI
18	Jan. 19,1996	Bern, Switzerland	OFMET ("Backup")
19	Nov. 20,1996	Braunschweig,Ger.	PTB
20	March 18, 1997*	London, England	NPL

*Since 1997, NIST has responded to requests for single SRPs from Australia, Spain, and, in 2002, 2 in Bureau Internationale des Poids et Mesures (BIPM) in France.

A visit to the NIST website on the SRP will provide details about the current system. It will also clarify that NIST has been working out an arrangement with the BIPM, with the goal of the BIPM taking over international support for the growing worldwide SRP network, over the next 5 years. NIST will still provide support to the U.S.(EPA) network.

EPA Traceability Protocol for ...Gaseous Calibration Standards-Status and Changes

Due to problems with the reliability/variability of the vendor-certified accuracy of the standard gases bought by state, local, and EPA Regional, and ORD laboratories for use to calibrate ambient air gaseous monitors, EPA established and has modified and expanded the scope of its Traceability Protocol for Certifying Gaseous Calibration Standards. In the late1980s, EPA ORD started reporting the results of a relatively small Protocol Gas verification program. Although sample size was small, probably not statistically representative, and had a relatively very low cost, vendors paid attention. This conclusion is indicated by the fact that the results improved over the 4-5 years of the program (paper at this meeting and session by John Schakenbach,U.S. EPA). Access to reports of the ORD verfication program can be found through the AMTIC website that contains the list of ORD reports and publications.



After ORD's QA service program divestment to OAQPS, the verification program was not continued. However, EPRI (ca.1998), and then EPA (2003-2004), in response to complaints by individuals from the user community, and some requests for re-institution of EPA-approved verification from some members of the gas vendor community, each performed an additional blind sampling study, and found that, without the program, significant problems, across pollutants, had again occurred. EPA is therefore looking into a vendor-funded, EPA-approved, 3rd party-operated, blind sampling, publicly-reported verification program.

In addition, the author has received specific corroborating statements from 2 long time east coast ambient air monitoring /auditing staff members, one from EPA Region 2, one from the State of West Virginia. In Region 2 , 6-10 cylinders are checked against their vendor centrations each year, and, on average, 1-2 per year are found to be incorrect, as much as 5% (NO)-10%(NO2). In West Virgina, problems identified were 1) dirty wetted surfaces on (cylinder) valves (see example photograph), and 2) some cylinders are not stable over their certified 2 year “shelf”life.

EPA has continued to hold internal and external meetings, and proposed alternative options to the vendors and NIST, the proposed benchmark for the analytical verfication(by both EPA and the vendors). EPA has responded to requests for action by EPA, inorder to get the necessary cooperation from the vendors. Proposed ambient air related CFR wording regarding the verfication has been prepared and submitted by OAQPS. Another group has agreed to add verification wording to its Protocol requirement. Our ORD NRMRL team member and Protocol Specialist has

been obtaining vendor and other stakeholder comments on proposed changes for the Protocol, and preparing changes. An IAG has been prepared for getting the NIST support to the analytical component of the verification. OAQPS has proposed 2 different blind sampling methods for acquiring the cylinder samples for the verification the 2 user communities- source and ambient, which we hope will be practical and acceptable tothe stakeholders.

Proposed Changes to 40 CFR Part 58- Brief Traceability Infrastructure Clarification

As part of the implementation of the current EPA Ambient Air Monitoring Strategy, currently under nationwide discussion, including CASAC subcommittee review, CFR changes have been proposed by OAQPS which include the addition of specific references, in 40 CFR Part 58, Appendix A, to the three components of the traceability infrastructure addressed in this paper. Updates and additions to the material currently in the websites are accessible at the following urls: http://www.epa.gov/ttn/amtic/qa or http://www.epa.gov/ttn/emc/news.html, for NPAP and the EPA Gas Protocol, respectively; and currently at the NIST website for the SRP, at http://www.cstl.nist.gov/nist839.03/ozone.html. Information about the EPA network can be obtained through the EPA author and network operating staff.

Using the Through The Probe Laboratory at Sites with Large Sampling Manifolds

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Abstract

Region 2 is a participant in EPA's Through The Probe (TTP) Quality Assurance auditing program in which independent in situ audits of ambient air quality monitors are conducted via the probe and manifold instead of directly to the back of the instrument. EPA Region 2 and its contractors maintain and operate a fully outfitted TTP laboratory consisting of a trailer with tow vehicle, gas standards, CO and Ozone analyzers, a Gas Phase Titration device, glass flow manifolds, and a 150 foot long by ½" diameter stainless steel jacketed Teflon presentation line. Additionally, this trailer is to be used for Quality Assurance audits in EPA Regions 1 and 3.

The trailer, as typically configured, can deliver a maximum of 14.5 liters per minute of audit gas through the presentation line to the instruments under test. Typical instruments under audit require 0.75 to 1.5 liters per minute of flow. As such, the TTP laboratory is optimally suited for auditing air monitoring stations where the sum total of sample demand is typically less than 13.5 liters per minute, in order to allow allowing for proper venting of the presentation line/instrument manifold interface .

In EPA Region 2, as well as in many of the monitoring stations in EPA Regions 1 and 3, State and Local instruments are not coupled to an individual manifold, but rather to a large common manifold made of borosilicate glass and varying in size from 1 inch to 4 inches in diameter. The connection from the monitoring instrument to the common manifold is achieved through a 1/4 inch Teflon "pigtail." In order to meet EPA sample residence time regulations, these large glass manifolds are typically equipped with "squirrel cage" type blowers at the back end of the manifold. Flows through the manifold are in the range of 25-70 liters per minute. In order to audit these large manifolds with the TTP laboratory, the manifold flow must be reduced, either through a reduction in voltage to the blower motor, blocking off of portions of the manifold, or disconnecting the blower. If this is not done, the blower motor is prone to failure due to its inability to handle even slight rises in static pressure. As a result, residence time in the manifold would be greater than EPA requirements, and furthermore, failed audit results could be contested as not being representative of field conditions.

In order to address these problems, EPA Region 2, with financial and technical assistance from EPA's Office of Air Quality, Programs, and Standards (OAQPS) , designed and implemented a test site to evaluate the TTP laboratory under conditions similar to those found in the field in EPA Regions 1,2, and 3. The test site consists of a 2" glass manifold 10 feet in length and a suite of Region 2's in-house gas analyzers connected to the manifold via 1/4 inch Teflon pigtails. Audits conducted at the test site showed that the current TTP laboratory can satisfactorily conduct an audit under such conditions, despite the increased residence times necessitated by the 14 liters per minute maximum output available at the TTP presentation line. Furthermore, equilibration times were not markedly increased with the common manifold and were well within values found by other TTP laboratories when auditing systems with one instrument per manifold.
Region 2 also designed and built, with OAQPS financial and technical support, a high volume delivery system capable of delivering up to 100 liters per minute of ozone, sulfur dioxide, carbon monoxide, and nitric oxide at typical audit concentrations. The system is built around a "brute force" approach, utilizing a 3/4 horsepower compressor, large scrubbers, mass flow controllers, a commercial ozone generator and ½" Teflon tubing. The

TTP presentation line is utilized, as are the on-board CO and Ozone analyzers. The system is sufficiently portable to be stored in the TTP trailer using the existing cabinet space. Preliminary testing has indicated positive results for this system.

Introduction

Region 2 is a participant in EPA's Through The Probe (TTP) Quality Assurance auditing program in which independent in situ audits of ambient air quality monitors are conducted via the probe and manifold instead of directly to the back of the instrument. EPA Region 2 and its contractors maintain and operate a fully outfitted TTP laboratory consisting of a trailer with tow vehicle, gas standards, CO and Ozone analyzers, a Gas Phase Titration device, glass flow manifolds, and a 150 foot long by ½" diameter stainless steel jacketed Teflon presentation. Additionally, this trailer is to be used for Quality Assurance audits in EPA Regions 1 and 3.

The trailer, as typically configured, can deliver a maximum of 14.5 liters per minute (lpm) of audit gas through the presentation line to the instruments under test. Typical instruments under audit require 0.75 to 1.5 liters per minute of flow. As such, the TTP laboratory is optimally suited for auditing air monitoring stations where the sum total of sample demand is typically 13.5 liters per minute, allowing 1 lpm for venting of the presentation line/instrument manifold interface .

In EPA Region 2, as well as in many of the monitoring stations in EPA Regions 1 and 3, State and Local instruments are not coupled to an individual manifold, but rather to a large common manifold made of borosilicate glass and varying in size from 1 inch to 4 inches in diameter. The connection from the monitoring instrument to the common manifold is achieved through a 1/4 inch Teflon "pigtail." In order to meet EPA sample residence time regulations, these large glass manifolds are typically equipped with "squirrel cage" type blowers at the back end of the manifold. Flows through the manifold are in the range of 30-70 liters per minute. In order to audit these large manifolds with the TTP laboratory, the manifold flow must be reduced, either through a reduction in voltage to the blower motor, blocking off of portions of the manifold, or disconnecting the blower. If this is not done, the blower motor is prone to failure due to its inability to handle even slight rises in static pressure. As a result, residence time in the manifold would be greater than EPA requirements, and furthermore, failed audit results could be contested as not being representative of field conditions.

Materials and Methods

In order to address the issue of TTP laboratory performance in a manifold situation, EPA Region 2, with financial and technical assistance from EPA's Office of Air Quality, Programs, and Standards (OAQPS) , designed and implemented a test site at Region 2's Edison, NJ Office, to evaluate the TTP laboratory under conditions similar to those found in the field in EPA Regions 1,2, and 3. The test site consists a glass manifold connected to Region 2's in-house monitoring instrumentation through individual "pigtails" of 1/4" Teflon tubing of 2- feet in length. The

manifold is constructed of 3 sections of 2" I.D. borosilicate glass; a 6 foot length, a 90 degree elbow joint, and a 4 foot length with 4 taps for the Teflon pigtails. Region 2's in house instrumentation consists of Thermo Environmental CO, SO_2, O_3, and NO_x analyzers. The manifold is mounted outdoors, and the instruments are in the Region 2 laboratory building. This maximizes protection for the instruments while providing easy access to the TTP trailer. The manifold is shielded from sunlight with aluminum foil. The manifold system has an approximate volume of 18 liters, which combined with the 6 liters of volume present in the TTP presentation line, results in a total system volume of 24 liters. The resulting residence time of the audit sample was computed to be 1.6 minutes.

Delivery of audit gases from the TTP trailer is accomplished by an API 701 zero air supply, delivering 16 liters per minute of gas at 35 psi to an Environics 9100 gas phase titration calibrator. The Environics 9100 is used for ozone generation and to blend in gas from a tri-blend cylinder containing SO_2, NO and CO. The Environics 9100 delivers its output to a rear manifold that feeds 14.5 lpm of gas to the instruments under test via a presentation line consisting of a 150 foot long, ½" diameter Teflon line sheathed in braided stainless steel. A tap from the rear manifold feeds a front manifold that distributes approximately 1.5 lpm (total) to the TTP's 2 assay instruments, a Thermo 49CPS ozone calibrator configured as an analyzer, and a Thermo 48C CO analyzer. The front manifold has an additional line that feeds a vent to atmosphere that is monitored via a front panel rotameter. A needle valve is used to gate flow from the rear manifold to the front manifold and to ensure that the front manifold is not pressurized. The total volume of the back of the analyzer system, including the 150 foot long ½" diameter presentation line was calculated to be 6 liters, which, at the 14.5 lpm flow rate would give a residence time near 25 seconds.

Ozone concentrations generated by the TTP laboratory are assayed by the Thermo 49CPS attached to the front manifold, with an adjustment for ozone line losses. This line loss adjustment is determined quarterly and is predicated on the difference in ozone concentrations observed when the front manifold is either fed by the rear manifold, as during normal operation, or by the presentation line. During the line loss test, excess flow from the presentation line is vented by a tee that is placed between the presentation line and the needle valve controlling flow to the front manifold.

CO concentrations generated by the TTP are assayed via the Thermo 48C fed by the front manifold. SO_2 and NO concentrations are determined through a proportional calculation derived from the CO analyzer response, since all gases are delivered at a constant ratio from a tri-blend cylinder. The tri-blend cylinder has NIST traceable certification for the concentration of CO, SO_2, NO and NO_x. NO_2 concentrations are calculated during the gas phase titration of NO with ozone by:

1) determining NO_x concentrations from the TTP Thermo 48C readings for CO,
2) Using the readings from the NO analyzer under test, adjusted for the regression relationship between the analyzer NO readings and actual NO concentration, which is established during the NO portion of the audit,

3) Subtracting the NO concentrations determined in step 2 from the NO_x concentrations determined in step 1.

In the study presented below, we tested to find the difference between delivering the audit gases through the glass manifold system and delivery of gases directly to the back of the audited instruments. The TTP laboratory trailer was used to generate audit points for Ozone, CO, SO_2, NO and NO_2 at >80%, 50%, and <20% of the instruments' upper range limit. Audit gas was delivered to the glass manifold system using the TTP presentation line to provide 14.5 lpm of gas to the manifold, with the audited instruments drawing samples from the manifold via the 1/4" o.d., 20 foot long Teflon pigtails. Attachment of the TTP presentation line to the manifold was accomplished by the use of a 2" silicone stopper through which a ½" i.d. Teflon tube was inserted. The ½" o.d. fitting on the presentation line was then mated through a friction fit to the silicone stopper/Teflon tube assembly. Teflon tape was used to secure the friction fit.

Gases were provided to the instruments at the back of the analyzer through a Teflon ½" to 1/4" reducing sleeve mated to a stainless steel 4-way cross tee. Two legs of the cross were attached to the back of the analyzers, and one leg of the cross was attached to a 6 foot length of 1/4" Teflon tubing vented to atmosphere. At the first test point, sample was fed to the instruments via the glass manifold until stable readings were achieved. Then, using the same concentration, the presentation line was shifted to the back of the analyzer delivery system. After stable readings were obtained and recorded, a new concentration was generated. After stability was achieved and the results recorded, the presentation line was shifted back to the glass manifold. All test points were generated in this manner, going back and forth between the glass manifold and the back of the analyzer. TTP laboratory instruments were calibrated pre- and post- audit according to the Standard Operating Procedures for TTP Audits. Stability was defined as a 5 minute interval with an instrument response variability of ±0.2 ppm for CO instruments and ±0.002 ppm for all other pollutants. The 5 minute results were then averaged.

Results

Table 1. Ozone Audit Results
TTP Lab vs. Station with Glass Manifold vs. Back of the analyzer gas delivery

Glass Manifold			Back Of Analyzer			
TTP Ozone (ppm)	**Station Ozone (ppm)**	**Station vs. TTP Percent Difference**	**TTP Ozone (ppm)**	**Station Ozone (ppm)**	**Percent Difference**	**Difference in % Dif. Between Manifold and Back**
0.000	**0.000**		**0.000**	**0.000**		
0.420	**0.418**	**-0.5%**	**0.422**	**0.421**	**-0.2%**	***-0.3%***
0.186	**0.184**	**-1.2%**	**0.186**	**0.187**	**0.3%**	***-1.5%***
0.074	**0.074**	**0.1%**	**0.074**	**0.074**	**-0.3%**	***0.4%***
0.000	**0.000**		**0.000**	**0.001**		

Table 1, Ozone Audit Results, shows the concentrations of ozone generated and assayed at the TTP Laboratory and the reported results from the Region 2 in-house instrumentation, using either the 2" glass manifold or the back of the analyzer path for the presentation of audit gas. As can be seen from the table, the differences between the 2 presentation methods typically differed by less than 1%, except in the case of the 0.186 ppm midpoint, where the difference between the 2 methods was 1.5%.

Table 2. Carbon Monoxide Audit Results
TTP Lab vs. Station with Glass Manifold vs. Back of the analyzer gas delivery

	Glass Manifold		Back Of Analyzer		
TTP CO (ppm)	**Station CO (ppm)**	**Percent Difference**	**Station CO (ppm)**	**Percent Difference**	**Difference in % Dif. Between Manifold and Back**
0.2	**0.3**		**0.3**		
39.9	**41.6**	**4.2%**	**41.4**	**3.7%**	***0.7%***
18.8	**19.5**	**3.5%**	**19.3**	**2.6%**	***0.9%***
7.5	**8.3**	**11.1%**	**8.6**	**14.4%**	***-3.3%***
0.2	**0.8**		**0.9**		

Table 2, Carbon Monoxide Audit Results, shows the concentrations of carbon monoxide generated and assayed at the TTP Laboratory and the reported results from the Region 2 in-house instrumentation, using either the 2" glass manifold or the back of the analyzer path for the presentation of audit gas. For all points except the 7.5 ppm TTP audit point, the results were within 1%. Even at this point, however, the difference between the 2 delivery system, in absolute terms, was within 0.3 ppm.

Table 3. Sulfur Dioxide Audit Results

TTP Lab vs. Station with Glass Manifold vs. Back of the analyzer gas delivery

	Glass Manifold		Back Of Analyzer		
TTP SO_2 (ppm)	**Station SO_2 (ppm)**	**Percent Difference**	**Station SO_2 (ppm)**	**Percent Difference**	**Difference in % Dif. Between Manifold and Back**
0.000	**0.000**		**0.000**		
0.402	**0.403**	**0.4%**	**0.403**	**0.4%**	***0.0%***
0.190	**0.189**	**-0.3%**	**0.189**	**-0.3%**	***0.0%***
0.076	**0.075**	**-0.7%**	**0.074**	**-2.0%**	***1.3%***
0.002	**0.000**		**0.000**		

Table 3, Sulfur Dioxide Audit Results, shows the concentrations of sulfur dioxide generated and assayed at the TTP Laboratory and the reported results from the Region 2 in-house instrumentation, using either the 2" glass manifold or the back of the analyzer path for the presentation of audit gas. For all points except the 0.076 ppm TTP low concentration audit point, the results were less <0.1%. within 1% regardless of the delivery system. Even at the low concentration audit point, the difference between the 2 systems, in absolute terms, was 0.001 ppm.

Table 4. Nitric Oxide Audit Results

TTP Lab vs. Station with Glass Manifold vs. Back of the analyzer gas delivery

	Glass Manifold		Back Of Analyzer		
TTP NO (ppm)	**Station NO (ppm)**	**Percent Difference**	**Station NO (ppm)**	**Percent Difference**	**Difference in % Dif. Between Manifold and Back**
0.004	**0.000**		**0.000**		
0.417	**0.418**	**0.3%**	**0.425**	**2.0%**	***-1.7%***
0.270	**0.271**	**0.3%**	**0.277**	**2.5%**	***-2.2%***
0.166	**0.167**	**0.6%**	**0.169**	**1.8%**	***-1.2%***
0.084	**0.082**	**-2.3%**	**0.083**	**-1.1%**	***1.2%***
0.004	**0.000**		**0.000**		

Table 4, Nitric Oxide Audit Results, shows the concentrations of nitric oxide generated and assayed at the TTP Laboratory and the reported results from the Region 2 in-house

instrumentation, using either the 2" glass manifold or the back of the analyzer path for the presentation of audit gas. Percent differences between the delivery systems was generally <2%, with the exception of the 0.270 ppm audit point where a difference of 2.2% was noted.

Table 5. Total Oxides of Nitrogen Audit Results
TTP Lab vs. Station with Glass Manifold vs. Back of the analyzer gas delivery

	Glass Manifold		Back Of Analyzer		
TTP NO_x (ppm)	**Station NO_x (ppm)**	**Percent Difference**	**Station NO_x (ppm)**	**Percent Difference**	**Difference in % Dif. Between Manifold and Back**
0.004	**0.000**		**0.000**		
0.417	**0.418**	**0.3%**	**0.425**	**2.0%**	***-1.7%***
0.270	**0.273**	**1.0%**	**0.277**	**2.5%**	***-1.5%***
0.166	**0.167**	**0.6%**	**0.169**	**1.8%**	***-1.2%***
0.084	**0.083**	**-1.1%**	**0.083**	**-1.1%**	***0.0%***
0.004	**0.000**		**0.000**		

Table 5, Total Oxides of Nitrogen Audit Results, shows the concentrations of NO_x generated and assayed at the TTP Laboratory and the reported results from the Region 2 in-house instrumentation, using either the 2" glass manifold or the back of the analyzer path for the presentation of audit gas. For all points, the greatest difference between the 2 delivery systems was found to be <1.7%.

Table 6. Nitrogen Dioxide Audit Results
TTP Lab vs. Station with Glass Manifold vs. Back of the analyzer gas delivery

Glass Manifold			Back Of Analyzer			
TTP NO_2 (ppm)	**Station NO_2 (ppm)**	**Percent Difference**	**TTP NO_2 (ppm)**	**Station NO_2 (ppm)**	**Percent Difference**	**Difference in % Dif. Between Manifold and Back**
0.001	**0.001**		**0.001**	**0.000**		
0.327	**0.328**	**0.4%**	**0.328**	**0.337**	**2.7%**	***-2.3%***
0.179	**0.182**	**1.5%**	**0.179**	**0.185**	**3.5%**	***-2.0%***
0.077	**0.078**	**1.1%**	**0.079**	**0.078**	**-0.7%**	***1.9%***

Table 6, Nitrogen Dioxide Audit Results, shows the concentrations of NO_x generated and assayed at the TTP Laboratory and the reported results from the Region 2 in-house instrumentation, using either the 2" glass manifold or the back of the analyzer path for the presentation of audit gas. For all NO_2 points, with the exception of the initial zero point, the NO concentrations were held to a range of 0.088-0.090 ppm, as per 40CFR Part 58 App. A 3.2.1.2 and 3.2.1.3, which specify that for all NO_2 audit points, NO must remain in the audit sample at a

concentration > 0.080 ppm and that the NO should not be "substantially higher" than 0.080 ppm. The difference between the 2 methods of delivery was typically <2%, with the exception of the high NO_2 point where a difference of 2.3% was seen. The average converter efficiency for the glass manifold system was 99%, whereas the back of the analyzer system had an average converter efficiency of 98.2%. A conversion efficiency of 100% ± 4% is the required criterion for this parameter.

Discussion

The results of the study presented above indicates that differences between the glass manifold and the back of the analyzer delivery system had small but generally consistent differences. The back of the analyzer systems tended to show higher concentrations than the glass manifold systems, particularly with the Ozone and Oxides of Nitrogen Audits. Nevertheless these differences were small, typically near 1% with Ozone, and close to 2% for oxides of nitrogen, and these findings were not consistent at all concentration levels tested. Therefore, there is a possibility that the constant switching from manifold to the back of the analyzer could be a factor in these results, as this could affect the equilibration of gases in the respective systems. Even though equilibration time for the initial manifold high concentration points was 2.5 hours, subsequent points were taken at 20 minute intervals, after a stable 5 minute result was obtained. The manifold system, with its larger total volume and surface area would be more likely to suffer from equilibration time related losses. Furthermore, the outdoor glass manifold, was at ambient temperature, which at the time of the experiment varied from 40 to 30 degrees Fahrenheit over the course of the audit. The back of the analyzer system was at room temperature. Nevertheless, 50 feet of the presentation line going from the TTP trailer to the delivery systems was always kept outdoors.

Conclusion

The results of the comparison of the two systems indicates close agreement between them, typically near 1% for CO, SO_2, and Ozone, and 2% for oxides of nitrogen audits. The suitability of this system for TTP audits with manifold-based systems appears to be well founded, particularly since the acceptance criteria for the non-ozone audits specify a limit of ±15% bias for passing the audit, and a limit of ±10% as a warning level. Ozone criteria are specified with a limit of ±10% bias for passing the audit and a ±7.5 limit for a warning level. Since differences between the 2 systems were typically 1% for ozone, the lower allowable bias criteria for ozone audits would not predispose a station to failure due to systemic biases with the delivery system employed.

To address issues where a potential failed audit in a large manifold-based system, for example, where the indicated bias exceeded the EPA criteria by 1% to 2%, the TTP system operator will be instructed to conduct a back of the analyzer assay in order to verify that the source of the error is manifold related. Should this appear to be the case, a re-audit would occur using a high

volume audit system, capable of providing flow normally used at this site, up to 100 lpm. Typical manifold flows in Region 2 have been measured and are on the order of 25-50 lpm. This high volume system is currently being built and evaluated. Its suitability for auditing is constrained by the fact that it requires large amounts of audit gas, and necessitates traveling with substantial amounts of extra equipment, including a 3/4" horsepower air compressor, large canisters of desiccant, mass flow controllers, and additional regulators and tubing. Additionally, the TTP Laboratory trailer was not planned for this type of system; as a result, traveling with this system is difficult due to the added weight, storage space, and mounting placement required to outfit this system for standard audits. However, for special purpose audits, such as a follow-up to a failed audit, where the manifold is indicated as a source of error, use of the high flow system would be practical and recommended.

Acknowledgments

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Literature Cited

United States Code of Federal Regulations, 2005, Part 40, Chapter 58, Appendix A

United States Environmental Protection Agency, 2004, Field Standard Operating Procedures for the EPA TTP National Performance Evaluation Program, Chapter 6, Revision 2.3

Attachments

TTP spreadsheet @back of analyzer v7.4
TTP spreadsheet @manifold v7.4